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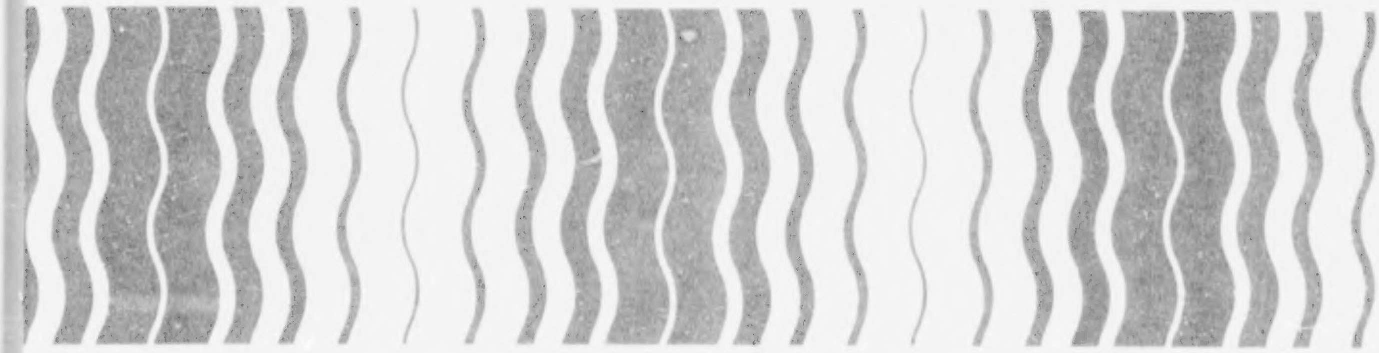
Pesticide Registration Standard



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PESTICIDE REGISTRATION STANDARD

ISOPROPALIN

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Chapter 1

HOW TO REGISTER UNDER A REGISTRATION STANDARD

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Organization of the Standard

This first chapter explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second chapter sets forth the requirements that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining chapters, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive (and having so received) deliver or offer to deliver, to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

> "(A) its composition is such as to warrant the proposed claims for it;
> (B) its labeling and other material required to be submitted comply with the requirements of this Act;
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks and benefits associated with the use of the proposed pesticide. But the established approach to making these findings has been found to be defective on two counts:

First, EPA and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product by product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product by product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advance in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even likely that materials may have been lost from the data files. When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [See FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the product by product approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have, compliance with standards of toxicity, composition, labeling, and packaging, and satisfaction of the data compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly-designed label precautions are strictly followed. Thus the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted-use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use," or not classified at all, is available for use by any individual who is in compliance with State or local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in the second chapter.

Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute his product in commerce, must apply for reregistration. His application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

"Product Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Residue Chemistry, and Ecological Effects. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 22, 1978), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement was actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familar to registrants. Data which we have found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaluation of other products, depending upon the composition, formulation type, and intended uses of the product in question. The Standard states which data requirements apply to which product categories. (See the second chapter.)

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

(A) data that is "product specific," i.e., data that relates only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

(B) "generic" data that pertains to the properties or effects of a particular ingredient, and thus is relevant to an evaluation of the risks and benefits of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition.

The Agency requires certain "product specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product specific" data on any product other than the applicant's is irrelevant, unless the other product is closely similar in composition to the applicant's. (Where it has been found practicable to group similar products for purposes of evaluating, with a single set of tests, all products in the group, the Standard so indicates.) "Product specific" data on the efficacy of particular end-use products is also required where the exact formulation may affect efficacy and where failure of efficacy could cause public health problems.

All other data needed to evaluate pesticide products concerns the properties or effects of a particular ingredient of products (normally a pesticidally active ingredient, but in some cases a pesticidally inactive, or "inert," ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient [e.g., the acute LD_{50} of the active ingredient in its technical or purer grade; see proposed 40 CFR 163.81-1(a), 43 FR 37355].

Other "generic" data are required to evaluate all products which contain both a particular ingredient and are intended for certain uses (see, e.g., proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use-pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally could be used to make an end-use, food-crop pesticide. But if an end-use product's label specified it was for use only in ways that involved no food/feed exposure and no repeated human exposure, the subchronic oral dosing study would not be required to evaluate the product's safety; and if a manufacturing-use product's label states that the product is for use only in making end-use products not involving food/feed use or repeated human exposure, that subchronic oral study would not be relevant to the evaluation of the manufacturing-use product either.

If a registrant of a currently registered manufacturing-use or end-use product wishes to avoid the costs of data compensation [under FIFRA Section 3(c)(1)(D)] or data generation [under Section 3(c)(2)(B)] for "generic" data that is required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his product. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

Data Compensation Requirements under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration, or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. The data for which compensation must be offered is all data which is described by all the following criteria:

(1) the data were first submitted to EPA (or to its predecessor agencies, USDA or FDA), on or after January 1, 1970;

(2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit, an amendment adding a new use to a registration, or for reregistration, or to support or maintain an existing registration;

(3) the data are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product's composition and intended use pattern(s);

(4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

(5) the data are not those for which the applicant has been exempted by FIFRA Section 3(c)(2)(D) from the duty to offer to pay compensation. (This exemption applies to the "generic" data concerning the safety of active ingredient of the applicant's product, not to "product specific" data. The exemption is available only to applicants whose product is labeled for end-uses for which the active ingredient in question is present in the applicant's product because of his use of another registered product containing that active ingredient which he purchases from another producer.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D).

An applicant would never be required to offer to pay for "product specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product; that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

Each applicant for registration or reregistration of a manufacuturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

Obtaining Data to Fill "Data Gaps"; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have never been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registrability decisions) and have not been located in the published literature search that EPA conducted as part of preparing this Standard. Such instances of missing but required data are referred to in the Standard as "data gaps".

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a section 3(c)(2)(B) order, his product's registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in its summary second chapter, the "generic" data gaps and notes the classes of products to which these data gaps pertain. The Standard also points out that to be registrable under the Standard, a product must be supported by certain required "product specific" data. In some cases, the Agency may possess sufficient "product specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product specific" data gaps on a product by product basis. (Although the Standard will in some cases note which data that EPA does possess would suffice to satisfy certain "product specific" data requirements for a category of products with closely similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps -- whether that data in question is "product specific" or "generic" -- in accordance with a schedule.

Persons who wish to obtain registrations for new products under this Standard will be required to submit (or cite) sufficient "product specific" data before their applications are approved. Upon registration, they will be required under Section 3(c)(2)(B) to take appropriate steps to submit data needed to fill "generic" data gaps. (We expect they will respond to this requirement by entering into cost-sharing agreements with other registrants who previously have been told they must furnish the data.) The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, product chemistry data, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the second chapter. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies of which may be requested from the Agency. When all the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and reissued for publication.

While the Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be pointed out in the Guidance Package.

II. REGULATORY CHAPTER

Introduction

This chapter presents the Agency decisions and the reasons supporting these decisions on the standards of product composition, toxicity, use, labeling and packaging that are required for the chemical 2,6-dinitro-N,N-dipropylcumidine. These decisions comply with the rules and regulations (40 CFR 162) used to implement the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA), and with the Agency's present regulatory policy. In this document, the Agency will refer to this compound primarily by its common name isopropalin. Its use or the use of the trade name in this document does not constitute endorsement or recommendation of use by this Agency.

Isopropalin, a dinitroaniline compound, is used as a soil-incorporated preplant or pretransplant herbicide for control of grasses and broadleaf weeds in tobacco fields. (For more information consult the Use Profile in Chapter IV page 41). Elanco Products Company, a Division of Eli Lilly and Company, Indianapolis, Indiana has submitted data in support of registration of an isopropalin product. These data may be cited by other registrants or applicants for registration, when appropriate, to support the registration(s) of their own product(s), provided they have offered and agreed to pay compensation, as required by FIFRA Sections 3(c)(1)(D).

The single product registered with isopropalin as an active ingredient is PAARLAN^{R}, emulsifiable concentrate. This product is produced by means of an integrated formulation system as defined in 43 FR 29708, July 10, 1978. Under this system the pesticide manufacturer registers an end-use product with an ingredient which is not registered as a manufacturing-use product, (i.e. the technical chemical containing the active ingredient is sold only after it is formulated into an end-use product). However, certain data are still required for the unregistered technical chemical (or purer grade of the active ingredient) to support registration of the end-use product.

REGULATORY POSITION

The Agency has evaluated the available data on the chemical 2,6-dinitro-N,N-dipropylcumidine and has determined that existing data indicate that isopropalin does not cause unreasonable adverse effects as cited in 40 CFR 162.11, with proper label directions and precautions. The isopropalin product currently registered may be reregistered subject to the conditions imposed for data requirements and labeling changes. New products may be registered under the standard and are subject to the same requirements.

In order to maintain the registration of an isopropalin product(s), the following are required.

1) Analytical data supporting a contamination level of less than one part per million N-nitrosamine, or exposure data which permit an estimation of risk which is acceptable to the Agency.

2) Data identified as necessary for maintaining registration for isopropalin use on tobacco.

3) Revision of the label.

REGULATORY RATIONALE

Special Isopropalin Issues Which Affect All Registered Products

Isopropalin is contaminated with the N-nitrosamine N-nitroso-di-n-propylamine (NDPA). Approximately 80% of all N-nitrosamines have been shown to be carcinogens. This finding prompted the Agency to require analyses of certain pesticide products which were most likely to be contaminated with N-nitrosamines (42 FR 51640). A proposed policy on N-nitrosamines has also been issued with specific requirements, (45 FR 42854) for products which are contaminated with N-nitroso compounds. The notice outlines the proposed risk criteria which guide the Agency in determining the registration status of new and previously registered pesticides.

The carcinogenicity of NDPA has been demonstrated by Druckery,[1/] et al., (1967), Reznik,[1/] et al., (1975), Pour,[1/] et al., (1973) and Dickhaus,[1/] et al., (1977). The highest NDPA values recorded for isopropalin were reported in 1978 by Cohen, S.Z., et al. (05006328) at 84 ppm to 87 ppm and in 1979 by Bontoyan (GS 0005-002) at 39 ppm to 54 ppm. A 1978 submission by Elanco (GS 0005-001) gives the highest level of contamination as 8.4 ppm NDPA. Analytical data were supplied supporting these values. In 1980 Elanco submitted a statement (GS 0005-003) asserting that the contaminant values of the formulated product were less than one part per million. Lot numbers and values of the NDPA contaminant were provided. No analytical data were provided to support these low values.

Some potential alternatives[2/] to isopropalin also have N-nitrosamine contaminants. Enide (diphenamid), Balan (benefin), and Prowl (pendimethalin), have N-nitrosamines at levels which range from less than 1 ppm to 135 ppm. Tillam (pebulate), and Tillam plus Devrinol (napropamide) are exceptions and are not contaminated with N-nitrosamines. Enide, Balan, and Prowl were found to be registrable under the proposed N-nitrosamine policy.

Taking this information into consideration the Agency has determined that the registration of isopropalin should be continued for the following reasons:

Elanco has stated that the NDPA contaminant levels for isopropalin is less than one part per million in recent batches of the emulsifiable concentrate. Elanco is known to possess the technology to lower the N-nitrosamine contaminant level in similar dinitroaniline products, as they have clearly demonstrated with the reduction of the NDPA content of Treflan, to a level that is less than one part per million.

1/ These studies are listed as reference material in section three of the Bibliography.

2/ Information on herbicides used on tobacco is from the "Report of use Data for Exposure Analysis of Isopropalin" a report prepared for EPA, and the "1980 Weed Control Manual" Meister Publishing Company.

A significant number of potential alternatives to isopropalin are contaminated with N-nitrosamines. Since these products which have similar use patterns have produced risk levels which were found to be acceptable to the Agency it is likely that the same will be determined for isopropalin.

However, the continued registration of isopropalin products is dependent upon the submission of data which demonstrates its safety.

The following data concerning the contaminant must be submitted:

- Analytical data on representative samples of the product showing acceptable levels of N-nitrosamine contamination according to the proposed N-nitrosamine policy (45 FR 42854).
- For the product, a statement of certified composition limits for isopropalin and the nitrosamine impurities, (43 FR 29709, July 10, 1978).
- Data demonstrating that N-nitrosamine impurities which exceed the certified limits are not produced during extended storage of the formulated product (43 FR 29711).
- A risk analysis for the NDPA contaminant as specified in the proposed N-nitrosamine policy if NDPA values are greater than one part per million.

CRITERIA FOR REGISTRATION UNDER THE STANDARD

To be subject to this standard, isopropalin products must meet the following conditions:

1. The product must meet the composition standards as specified.
2. The product must meet the acute toxicity standards as specified.
3. The product must meet the labeling standards as specified.
4. The applicant must submit all data specified in the section - Data Requirements and Data Gaps.
5. The applicant must offer, when applicable, to pay compensation to the extent required by 3(c)(1)(D) of the Federal Insecticide, Fungicide and Rodenticide Act [FIFRA], as amended, 7 U.S.C. 136(c)(1)(D).
6. The applicant must submit the application package in the required form as specified in this Standard and the accompanying guidance package.

The Elanco Products Company has submitted data in support of an isopropalin product and has not waived their rights to compensation for these data.

MANUFACTURING-USE PRODUCT FOR ISOPROPALIN

The registrant has registered their product as an Integrated-Formulation-System Product. Consequently, there are no manufacturing-use products registered. The technical material is formulated directly into an end-use product.

All data required for this type of registration, both generic and product specific, are the responsibility of the registrant of the formulated product.

Tolerances

Data to support the establishment of tolerances in or on food and feed are normally supplied by the first producer of a technical chemical.

At this time, there are no registered food uses for isopropalin. Isopropalin was initially registered on February 9, 1972, for pre-emergence use on tomatoes and peppers at a maximum rate of 2 lbs/acre. Tolerances were simultaneously established for residue levels of 0.05 ppm for both crops (40 CFR 180.313). These tolerances are not CODEX tolerances. Later on, the registrant amended the label for tobacco use only and the recommended uses on food crops were removed from the label.

It should be noted that although the reported residues of isopropalin in or on tomatoes and peppers has not been discussed in the standard, it is considered adequate for a tolerance. Although the residue data is adequate, the toxicology data base is inadequate. There are no data on chronic feeding, oncogenicity, teratology, reproduction, mutagenicity and metabolism which are currently required as supporting data for tolerances.

Therefore, since there are no registered uses for this pesticide on tomatoes and peppers and the toxicology data base is deficient, the Administrator will propose issuance of a regulation to repeal these tolerances under the authority of the Federal Food, Drug and Cosmetic Act, Section 408(e) and 40 CFR 180.32.

FORMULATION(S)

EMULSIFIABLE CONCENTRATE ISOPROPALIN

Product Composition Standard

Under this Standard an emulsifiable concentrate of isopropalin of similar composition is acceptable for registration.

Acute Toxicity Limits

The Agency will consider for registration end-use products of any toxicity category for isopropalin products. However the registrant must incorporate the appropriate precautionary and use restriction statements into the label.

To be registered for a nondomestic, general use under this standard, the emulsifiable concentrate of isopropalin must have a classification of

Toxicity Category I through IV for each of the following effects:

- Acute Oral Toxicity
- Acute Dermal Toxicity
- Acute Inhalation Toxicity
- Primary Eye Irritation
- Primary Dermal Irritation

Data are required for acute inhalation, and primary dermal irritation. There are no data available for acute inhalation, and inadequate data available for primary dermal irritation. The primary eye irritation data cannot be recategorized since observations were not made past the seventh day. According to the criteria established in 1975 (40 CFR 162.10(h)(1)] the emulsifiable concentrate is a category I eye irritant. The Agency has adopted the criteria proposed by the National Academy of Sciences publication 1138 for categorization of the Primary Eye Irritation test and the Primary Dermal Irritation test. Revised testing protocols are now available (46 FR 7074). Since new testing may result in a reclassification to a lower toxicity category, the registrant may wish to repeat the Primary Eye Irritation Test. If the registrant does not wish to repeat this test then the labeling must be revised so that it is appropriate for a Category I eye irritant.

Use Patterns and Application Method

To be registered under this standard, emulsifiable concentrate products of isopropalin may be used only as a pre-emergent herbicide in tobacco fields which are not rotated with food or feed crops.

Data requirements for rotational crops are listed on pages 23 and 61. These data are needed to support removal or change of the rotational crop restriction for isopropalin products. These data provide the necessary information for the selection of an appropriate time interval between application of isopropalin and the planting of a rotational crop so that residues will not occur in the crop. As an alternative the registrant may obtain a tolerance or an exemption from a tolerance for isopropalin in rotational or follow-up crops (46 FR 3018). The registrant does have the option of keeping the rotational crop restriction and not providing the data.

The Agency finds that current dosage rates and application methods are acceptable under this standard.

Data Gaps

The applicant proposing the registration of an emulsifiable concentrate of isopropalin for end-use must cite or submit the information on product chemistry, residue chemistry, environmental fate, ecological effects and toxicology of the proposed product. If the applicant establishes that a product is substantially similar to another product, for which the Agency has received acceptable acute toxicity tests, data from these tests may be cited provided compensation has been offered to the submitters of these studies. The Agency will consider both active and inert ingredients in making the determination of substantially similar products.

Data supporting the registration of isopropalin has been listed in chart form. The Agency has not received acceptable data for some tests which have been listed in the following charts (page 13 to 32).

Required Labeling

All emulsifiable concentrate products must bear appropriate labeling as specified in 40 CFR 162.10.

All labels and labeling intended for agricultural use products must bear the following statement: "This product must be applied in accordance with 40 CFR Part 170". Registrants may state the contents of 40 CFR Part 170 or additional statements.

The following changes are necessary for the PAARLAN, emulsifiable concentrate label:

1. The statement "Do not contaminate foodstuffs or feeds" must appear under the "Directions for Use" in the general restriction section.

2. The following rotational crop restriction must appear on the label: "Do not use in a crop rotation program for food or feed crops".

3. The "Environmental" subheading must be revised to "Environmental Hazards." This section must be revised in the following way:

   "This pesticide is toxic to fish. Do not directly apply to water. Do not contaminate water by cleaning of equipment or disposal of wastes.

4. The subheading "Storage" must be changed to "Physical or Chemical Hazards." This section must be revised to include the following:

   "Do not store near heat or open flame."

5. The statement, "It is a violaton of federal law to use this product in a manner inconsistent with its labeling" must appear directly under "Directions for Use."

6. A "Storage and Disposal" section must be added. This section must include the proper statements from the enclosure (pamphlet which accompanies product).

7. Additional revisions may be required when additional data are submitted.

If the registrant does not wish to repeat the primary eye irritation test, then the label must include statements appropriate for a Category I eye irritant. The following statements would have to be added to the PAARLAN, Emulsifiable concentrate label:

8. The signal word "DANGER" must appear on the front panel; delete the word "CAUTION".
9. The referral statement on the front panel must be revised to the following:

   "See back panel for additional precautionary statements."

10. The signal word "DANGER" must replace the word "CAUTION" on the back panel.

11. Preceeding the signal word "Danger" on the back panel, the heading "Precautionary Statements" and the subheading "Hazards to Humans and Domestic Animals" must appear. Delete the heading "Human" which now appears on the labeling.

12. The "Hazards to Humans and Domestic Animals" section must read as follows:

    "DANGER. Corrosive, causes eye damage. Do not get in eyes, on skin or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed or absorbed through the skin. Avoid breathing vapors or spray mist."

13. The statement of "Practical Treatment" heading must appear on the labeling. This section may appear directly following the "Hazards to Humans and Domestic Animals" section or following the signal word on the front panel. This section must include the following:

    "If in eyes : Flush with water for 15 minutes. Get immediate medical attention.

    If on skin : Wash with plenty of soap and water.

    If swallowed : Drink one or two glasses of water and induce vomiting by touching back of throat with finger. Do not give anything by mouth to an unconscious person. Get medical attention."

CHARTS

The following charts list the data requirements necessary for the reregistration of the Integrated-Formulation-System Product PAARLAN.

Since there are no registered Manufacturing-Use Products the responsibility for providing the generic and product specific data rest with the registrant of the formulated product.

Product-Chemistry (see Chapter III)
Data Requirements for the Integrated Formulation System Product Isopropalin[9]

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.61-3	Product identity and disclosure of ingredients	yes	68.6 % EC	yes	Elanco[1]	no
			Tech.	yes	Elanco[1]	no
163.61-4	Description of Manufacturing Process	yes	68.6% EC[2]	partial[4]	00002789 Elanco 00002559 Elanco	yes 24 months
		yes	Tech.	partial[4]	00002789 Elanco 00002559 Elanco	yes 24 months
163.61-5	Discussion on formation of unintentional ingredients	yes[3]	68.6% EC	partial[5]	GS0005-001 Elanco GS0005-002 Bontoyan GS0005-003 Elanco 05006328 Cohen 05001066 Keszthelyi 05001065 Keszthelyi	yes 24 months
		yes[3]	Tech.	partial[5]	GS0005-002 Bontoyan GS0005-003 Elanco 05006328 Cohen 05001066 Keszthelyi	yes 24 months
163.61-6	Declaration and certification of ingredient	yes[3]	68.6%	no	-	yes 6 months

1/ Elanco's Confidential Statement of Formula, Registration Jacket #1471-79.
2/ Implied in the requirement but not stated as such in the guidelines.
3/ Data provided with respect to these requirements must also address the nitrosamine contamination issue.
4/ A detailed description of the manufacturing process, composition of starting materials, and reaction solvents (including impurities), reaction temperatures and side reactions, packaging materials.
5/ A discussion of impurities associated with the manufacturing and formulating process are required.
9/ These data support the registration of the product PAARLAN only.

Isopropalin Product-Chemistry (see Chapter III)
Data Requirements for the Integrated-Formulation System Product Isopropalin[9]

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.61-7	Product analytical methods and data	yes	68.6% EC	yes	05001253 Decker 05001069 Matsunaga 05001063 Johnson 00002789 Elanco 00002559 Elanco GS0005-003 Elanco GS0005-001 Elanco 05001065 Keszthelyi 05001066 Keszthelyi	no
			Tech[6]	yes	00002591 Decker 05001253 Decker 05001069 Matsunaga 05001063 Johnson 00002789 Elanco 00002559 Elanco GS0005-003 Elanco GS0005-001 Elanco 00002590 Elanco 05001065 Keszthelyi 05001066 Keszthelyi	no
163.61-8(c)(1)	Color	yes yes	Tech. 68.6% EC	yes no	05001063 Johnson	no yes 6 months
163.61-8(c)(2)	Odor	yes yes	Tech. 68.6% EC	no no	- -	yes 6 months yes 6 months
163.61-8(c)(3)	Melting point	no [7]	-	-	-	no
163.61-8(c)(4)	Solubility	yes	Tech.	yes	00002559 Elanco 00002789 Elanco	no
163.61-8(c)(5)	Stability	yes	Tech.	partial[8]	05001063 Johnson 00002789 Elanco	yes 6 months
163.61-8(c)(6)	Octanol/water partition coefficient	yes	Tech.	no	-	yes 6 months

[6] Because an MUP is not registered, methods and data for impurities associated with the manufacture of technical isopropalin are required in addition to the analytical methods and data for the active ingredient.

[7] This property does not apply to isopropalin since it is a liquid at room temperature.

[8] The effects of small amounts of impurities (e.g., alkali, acids and metallic ions) on the stability of isopropalin have not been submitted.

[9] These data support the registration of the product PAARLAN only.

Isopropalin Product-Chemistry (see Chapter III)
Data Requirements for the Integrated Formulation System Product Isopropalin[9/]

Guidelines Citation	Name of Test	Are Data Required	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.61-8(c)(7)	Physical state	yes	Tech.	yes	05001096 Weber	no
		yes	68.8% EC	yes	Elanco[1/]	no
163.61-8(c)(8)	Density or specific gravity	yes	Tech.	no	-	yes 6 months
		yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(9)	Boiling point	yes	Tech.	no	-	yes 6 months
163.61-8(c)(10)	Vapor pressure	yes	Tech.	yes	05001063 Johnson 05001096 Weber	no
163.61-8(c)(11)	pH	yes	68.6% EC	no	-	yes 6 months
			Tech.	yes	05001096 Weber	no
163.61-8(c)(12)	Storage stability	yes	68.6% EC	partial[3/]	00002591 Decker	yes 6 months
163.61-8(c)(13)	Flammability	yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(14)	Oxidizing or reducing action	yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(15)	Explosiveness	yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(16)	Miscibility	yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(17)	Viscosity	yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(18)	Corrosion characteristics	yes	68.6% EC	no	-	yes 6 months
163.61-8(c)(19)	Dielectric Breakdown Voltage	no	-	-	-	-

[1/] Elanco's Confidential Statement of Formula, Registration Jacket #1471-79.

[3/] Data provided with respect to these requirements must also addresss the nitrosamine contamination issue.

[9/] These data support the registration of the product PAARLAN only.

Environmental Fate (see Chapter IV)
Data Requirements for the Integrated Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.62-7(b)	Hydrolysis	yes	Tech. or Radiolabeled Analytical Gr.	no	-	yes 24 months
163.72-7(c)	Photodegradation	yes	Tech. or Radiolabeled Analytical Gr.	partial1/	05001076 Parochetti 05001267 Kennedy	yes 24 months
163.62-8(b)	Aerobic soil metabolism	yes	Tech. or Radiolabeled Analytical Gr.	partial2/	00002473 Golab 05001257 Gingerich 00002814 Elanco 05001260 Golab	yes 24 months
163.62-8(c)	Anaerobic soil metabolism	yes	Tech. or Radiolabeled Analytical Gr.	partial2/	00002473 Golab 05001260 Golab 05001257 Gingerich 00002814 Elanco	yes 24 months
163.62-8(d)	Anaerobic aquatic metabolism	no	-	-	-	-
163.62-8(e)	Aerobic aquatic metabolism	no	-	-	-	-
-	Microbial metabolism (2) effects of microbes on pesticides	Reserved3/	-	-	-	-
	(3) effects of pesticides on microbes	Reserved3/	-	-	-	-

1/ Some data are available on photodegradation of isopropalin in soil, and no additional data in soil are required. However data are required on the photodegradation of isopropalin in water.

2/ Data characterizing the decline of parent compound are adequate. All other data such as the patterns of formation and decline of metabolites formed under aerobic conditions and differences in patterns of metabolism between aerobic and anaerobic soil conditions are required.

3/ The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

Environmental Fate (see Chapter IV)
Data Requirements for the Integrated Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
-	Activated sludge	Reserved[3]	-	-	-	-
163.62-9(b)	Leaching	Reserved[4]	-	-	-	-
163.62-9(c)	Volatility	no	-	-	05001267 Kennedy[5] 05001077 Parochetti 05001264 Harvey	-
163.62-9(d)	Adsorption/desorption	Reserved[4]	-	-	-	-
163.62-9(e)	Water dispersal	no	-	-	-	-

3/ The requirement for the submission of these data is currently being reserved pending the review and modification of the testing protocols. Consequently, the absence of acceptable data does not constitute a data gap.

4/ The requirement for the submission of these data is currently being reserved pending the receipt and evaluation of data on hydrolysis, photodegradation in water, aerobic and anaerobic soil metabolism, and rotational crops. Consequently the absence of acceptable data does not constitute a data gap.

5/ Although not required, these data were used for the Exposure Profile of the Standard.

Environmental Fate (see Chapter IV)
Data Requirements for the Integrated Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.62-10(b)	Terrestrial field dissipation					
	(1) Field & Vegetable crop	yes	EC	yes	00002473 Golab 05001260 Golab 05001084 Saghir 00002609 Starker 00002610 Steenwyk 00002611 Shoop 00002612 Hobbs 00002613 Watson 00002614 Humphreys 00002615 Keaton 00002616 Webster 00002621 Helmer 00002622 Webster 00002597 Eli Lilly 00002800 Elanco 00002801 Elanco 00002802 Elanco 00002798 Watson 00002797 Massey 05001267 Kennedy 05002135 Harvey 00003260 Elanco 05001083 Romanowski 05001088 Stoller	no
	(2) Tree fruit & nut crop uses	no	-	-	-	-
	(3) Pasture land uses	no	-	-	-	-
	(4) Domestic outdoor park	no	-	-	-	-
	(5) Rights of way, shelterbelts and related uses	no	-	-	-	-

Environmental Fate (see Chapter IV)
Data Requirements for the Integrated Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.62-10(c)	Aquatic field dissipation					
	(1) aquatic food crop uses	no	-	-	-	-
	(2) Aquatic noncrop uses	no	-	-	-	-
	(3) Specialized aquatic uses	no	-	-	-	-
163.62-10(d)	Terrestrial/ aquatic (forest) field dissipation	no	-	-	-	-
163.62-10(e)	Aquatic impact uses					
	(1) Direct discharge	no	-	-	-	-
	(2) Indirect discharge	no	-	-	-	-
	(3) Wastewater treatment	no	-	-	-	-

Environmental Fate (see Chapter IV)
Data Requirements for the Integrated Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.62-10(f)	Combination and tank mix field dissipation	no[6]	-	-	-	-
163.62-11(b)	Accumulation[7] in rotational crops	yes	Radiolabeled Analytical Gr. followed by formulation	partial[8]	05001260 Golab 00002535 Golab 00002509 Eli Lilly 00002558 Eli Lilly 00002507 Eli Lilly	yes 24 months
163.62-11(c)	Accumulation in irrigated crops	no	-	-	-	-
163.62-11(d)	Fish accumulation	Reserved[4]	-	-	-	-
163.62-11(e)	Special studies accumulation in aquatic noncrop uses	no	-	-	-	-

[4] The requirement for the submission of these data is currently being reserved pending the receipt and evaluation of data on hydrolysis, photodegradation in water, aerobic and anaerobic soil metabolism, and rotational crops. Consequently the absence of acceptable data does not constitute a data gap.

[6] Not applicable in single active ingredient standard.

[7] Removal of rotational crop restriction requires one of the following:

A) Environmental Fate data to support a rotation interval which does not result in a pesticide residue in the rotated crop;
B) A tolerance for the nontarget crop;
C) An exemption from a tolerance.

[8] Registrant must identify crops to be rotated with tobacco, provide data on the unidentified ^{14}C residues; provide ^{14}C and in-use field data to support a rotation interval that will result in no residues in selected rotated crops.

Residue-Chemistry (see Chapter V)
Data Requirements for an Integrated Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
-	Metabolism in Plants	no	-	-	-	no
-	Metabolism in Animals	no	-	-	-	no
-	Analytical Methods	no	-	-	-	no
-	Residue Data: Crops	yes	-	partial2/	00002506 Elanco1/ 05001260 Golab 1/ 00002477 Eli Lilly 00002554 Elanco 00002507 Eli Lilly 00002793 Johnson 00002795 Holzer	yes months
-	Residue Data: Processed Crops	no	-	-	-	no
-	Residue Data: Milk and Meat	no	-	-	-	no
-	Storage Stability	no	-	-	-	no

1/ Raw data are requested for this study.

2/ Raw data are requested for studies as footnoted.

Ecological Effects (see Chapter VI)
Data Requirement for the Integrated-Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.71-1	Avian Single-Dose Oral LD_{50}	yes	Tech.	no	-	yes 6 months
163.71-2	Avian Dietary LC_{50}	yes	Tech.	no	-	yes 6 months
163.71-3	Mammalian Acute Toxicity	no	-	-	-	-
163.71-4	Avian reproduction	no	-	-	-	-
163.71-5	Simulated and Actual Field Testing for Mammals and Birds	no	-	-	-	-
163.72-1	Fish Acute LC_{50}	yes	Tech.	partial[1/]	00002592 C West	yes 6 months
163.72-2	Acute Toxicity to Aquatic Invertebrate	yes	Tech.	no	-	yes 6 months

[1/] This data submitted is seriously deficient in that information on the test and test organisms parameters is lacking. Although the goldfish is not an acceptable test species, the Agency will reevaluate this study if missing data can be provided.

Ecological Effects (see Chapter VI)
Data Requirement for the Integrated-Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partially or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.72-3	Acute Toxicity to Estuarine and Marine Organisms	no	-	-	-	-
163.72-4	Embryolarvae and Life-cycle Studies of Fish and Aquatic Invertebrates	no	-	-	-	-
163.72-5	Aquatic Organism Toxicity and Residue Studies	no	-	-	-	-
163.72-6	Simulated or Actual Field Testing for Aquatic Organisms	no	-	-	-	-
163.121-1	Target Area Phytotoxicity	waiver[2/]	-	-	-	-
163.122-1	Nontarget Area Phytotoxicity Seed Germination Vegetative Vigor	yes	Tech.	yes	See attachment	no
163.122-2	Aquatic Marcrophyte	yes	Tech.	no	-	yes 24 months
163.122-2	Algae	yes	Tech.	no	-	yes 24 months

[2/] Discussion concerning the waiver of efficacy and phytotoxicity data is given in detail in the preamble to Proposed Subpart J, 45 FR 72950 - 72952.

Attachment

Bibliographic Citations for Nontarget area Phytotoxicity (Seed Germination and Vegetative Vigor) 163.122-1

Tomato

Author	Date	MRID
Ashton et al.	1970	00002575
Wilson	1972	00002633
Tisdell	1971	00002652
Putnam	1973	00002655
Elanco	1969	00002695
Lade	1969	00002696
Massey	1969	00002697
Massey	1969	00002698
Massey	1969	00002699
Massey	1969	00002700
Elanco	1969	00002701
Shoop	1969	00002702
Elanco	1969	00002703
Elanco	1969	00002704
Pafford	1969	00002705
Pafford	1969	00002706
Warner	1969	00002707
Steenwyk	1969	00002708
Steenwyk	1969	00002709
Steenwyk	1969	00002710
Steenwyk	1969	00002712
Steenwyk	1969	00002713
Cooper	1969	00002714
Elanco	1969	00002720
Elanco	1969	00002721
Elanco	1969	00002722
Helmer	1969	00002724
Helmer	1969	00002725
Helmer	1969	00002726
Elanco	1969	00002728
Elanco	1968	00002729
Elanco	1968	00002730
Humphreys	1968	00002731
Humphreys	1969	00002732
Elanco	1969	00002733
Massey	1969	00002734
Webster	1969	00002735
Keaton	1969	00002736
Elanco	1969	00002737
Helmer	1969	00002738
Elanco	1969	00002739
Elanco	1969	00002758
Elanco	1969	00003257
Fisher	1969	00002740
Hopen	1969	00002741
Greenfield	1969	00002742

Tomato (cont.)

Author	Date	MRID
Elanco	1969	00002715
Elanco	1969	00002716
Elanco	1969	00002717
Elanco	1969	00002718
Elanco	1969	00002719
Steenwyk	1970	00002820
Steenwyk	1970	00002822
Steenwyk	1970	00002823
Talbert	1974	00003252
Steenwyk	1970	00003262
Steenwyk	1970	00004151
Alban	1972	05001038
Anderson	1972	05001041
Orr	1974	05001074
Eshel	1972	05002134
Warner	1969	00002743
Monaco	1969	00002759
Keaton	1970	00002773
Steenwyk	1970	00002819
Cotton		
Webster	1970	00002487
Webster	1970	00002488
Keaton	1972	00002491
Pafford	1970	00002774
Overton	1972	05001075

Soybeans

Author	Date	MRID
Keaton	1972	00002491
Shoop	1970	00002770
Overton	1972	05001075
Harvey	1973	05002135

Peppers

Ashton	1970	00002575
Tweedy	1970	00002576
Univ. SWLA	1970	00002577
Monaco	1969	00002579
Keaton	1971	00002580
Alban	1969	00002581
Ogle	1969	00002582
Tweedy	1969	00002587
Massey	1969	00002746
Hobbs	1969	00002583
Steenwyk	1969	00002584
Elanco	1969	00002585
Massey	1969	00002756
Humphreys	1969	00002757
Keaton	1970	00002773
Humphreys	1976	00002775
Hobbs	1970	00003244
Hobbs	1970	00002562
Hobbs	1970	00002563
Warner	1970	00002564
Steenwyk	1970	00002565
Cooper	1970	00002566
Humphreys	1970	00002567
Humphreys	1971	00002568
Hobbs	1969	00002744
Elanco	1969	00003242
Hobbs	1969	00003243
Hobbs	1970	00002570
Hobbs	1970	00002571
Hobbs	1970	00003245
Chamberlain	1969	00002747
Warner	1969	00002748
Cooper	1969	00002749
Elanco	1958	00003258
Humphreys	1970	00002572
Humphreys	1969	00002573
Humphreys	1970	00002574
Elanco	1968	00002750
Elanco	1968	00002752
Helmer	1969	00002753
Eshel	1972	05002134

Fruits and Vegetables

Author	Date	MRID
Ashton	1970	00002575
Massey	1970	00002769
Chamberlain	1976	00002771
Overton	1972	05001075
Harvey	1977	05001263
Humphreys	1969	00002799
Harvey	1973	05002135
Eshel	1972	05002134

Toxicology (see Chapter VII)
Data Requirements for the Integrated-Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partaily or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard
163.81-1	Acute Oral Toxicity	yes	EC	yes	00002472 G Worth 00002472 H Worth	no
			Tech.[1]	yes	00002472 A Worth 00002472 B Worth 00002472 C Worth 00002472 G Worth 00002472 H Worth	no
163.81-2	Acute Dermal Toxicity	yes	EC	yes	00002472 J Worth	no
			Tech.[1]	yes	00002472 J Worth	no
163.81-3	Acute Inhalation Toxicity	yes	EC	no	-	yes 12 months
163.81-4	Primary Eye Irritation	yes	EC	no[2]	00002472 I Worth	no
163.81-5	Primary Dermal Irritation	yes	EC	no	-	yes 12 months
163.81-6	Dermal Sensitization	yes	EC	no	-	yes 12 months
163.81-7	Acute Delayed Neurotoxicity	no	-	-	-	-

1/ Some data on the technical material is required for an Integrated-Formulation-System Product. Although the data submitted are more than necessary, it has been used in support of this product's registration.

2/ Data submitted, (Worth; 00002472I), cannot be recategorized according to new criteria (NAS 1138). The registrant has the following options: a) use the existing data and revise product label so that it is appropriate for a Category I eye irritant or b) repeat the test using the protocol and evaluation criteria and revised label if necessary.

Isopropalin Toxicology (see Chapter VII)
Data Requirements for the Integrated-Formulation System Product Isopropalin

Guidelines Citation	Name of Test	Are Data Required for Outdoor Nondomestic Terrestrial, Tobacco Use?	Composition	Does EPA Have Data to Partaily or totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of standard?
163.82-1	Subchronic 21-Day Dermal Toxicity	no	-	-	-	-
163.82-2	Subchronic 21-Day Dermal Toxicity	no	-	-	-	-
163-82-3	Subchronic 90-day Dermal Toxicity	no	-	-	-	-
163.82-4	Subchronic Inhalation Toxicity	no	-	-	-	-
163.82-5	Subchronic Neurotoxicity	no	-	-	-	-
163.83-1	Chronic Toxicity	no	-	-	-	-
163.83-2	Oncogenicity	no	-	-	-	-
163.83-3	Teratogenicity	yes	Tech.	no	-	yes 12 months
163.83-4	Reproduction	no	-	-	-	-
163.84-2 through -4	Mutagenicity	yes	Tech.	no	-	yes 12 months
163.85-1	Metabolism	no	-	-	-	-

III. PRODUCT CHEMISTRY

Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. The Agency's guidelines (Subpart D) require registrants to provide quantitative composition data on all added ingredients, active and inert, which are equal to or greater than 0.1% of the product by weight.

To establish the composition of products proposed for registration, the Agency requires data and information not only on the manufacturing and formulation processes but also a discussion on the formation of manufacturing impurities and other product ingredients, intentional and unintentional. Further, to assure that the composition of the product as marketed will not vary from the composition evaluated at the time of registration, applicants are required to submit a statement certifying upper and lower composition limits for the added ingredients, and upper limits only for potentially hazardous impurities (e.g. nitrosamines).

In addition to the data on product composition, the Agency guidelines also require data to establish the physical and chemical properties both of the active ingredient and its formulations. For example, data are needed concerning the identity and physical state of the technical chemical and/or purer form of the active ingredient (e.g., melting and boiling point data, ambient vapor pressure and solubility). Data are also required on the properties of the formulated product in order to establish labeling cautions (e.g., flammability, corrosiveness or storage stability). The Agency uses these data to characterize each pesticide and to determine its environmental and health hazards.

DISCIPLINARY REVIEW

Product Chemistry Profile

Isopropalin or 2,6-dinitro-N,N-dipropylcumidine, belongs to the class of compounds known as the dinitroanilines. These compounds are often contaminated with nitrosamines, as is isopropalin, with nitrosodipropylamine (NDPA). Elanco has submitted data indicating that the level of NDPA contamination is quite low, but additional data are needed to show the contamination of representative samples of the end-use product at the time of production and after a storage period of one year.

The "Pesticide Use Pattern Profile" indicates that only one isopropalin product is marketed and it is for end-use -- PAARLAN Emulsifiable Concentrate (Registration No. 1471-79). Therefore the isopropalin product(s) is in the group of products defined by the guidelines as integrated-formulation-system products. Although the technical material (approximately 99% purity) is not registered, product chemistry data on the technical material, as indicated in the appropriate data gap section, are needed to support the registration of formulated products produced by an integrated-formulation-system. PAARLAN E.C. contains six pounds of isopropalin per gallon.

Data Requirements

The Product Chemistry data needed to support the registration of an Integrated-Formulation System Product are on pages 16-18. Preceding each data requirement is the section in the Proposed Guidelines for the Registration of Pesticides in the United States (43 FR 29696, July 10, 1978) that describes the type of data required.

Physical Hazard Precautionary Labeling

Manufacturing-use products and formulated products containing isopropalin should bear an appropriate label warning in accordance with the nature of the physical and chemical properties. Since much of this information has not been submitted, no recommendations for changes in labeling can be made at this time. When appropriate data have been submitted and evaluated, labeling changes may be necessary.

TOPICAL DISCUSSIONS

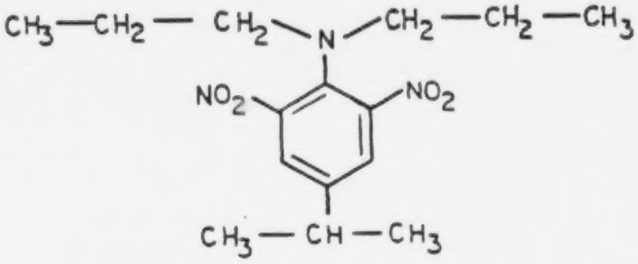
Corresponding to each of the Topical Discussions is the number of the section in the 'Proposed Guidelines for Registering Pesticides' in the United States (43 FR 29696, July 10, 1978) which explains the minimum data that the Agency requires in order to adequately assess Product Chemistry of manufacturing-use isopropalin products.

CHEMICAL IDENTITY 163.61-3

The American National Standards Institute (ANSI), in 1971, accepted "Isopropalin" as the common name for 2,6-dinitro-N,N-dipropylcumidine.

Elanco Products Company, Division of Eli Lilly and Company, is currently the only manufacturer of isopropalin. Elanco has submitted a Confidential Statement of formula which lists the ingredients of the product PAARLAN, (Registration Jacket 1471-79).

Molecular structure:



Chemical Nomenclature:

2,6-dinitro-N,N-dipropylcumidine

2,6-dinitro-N,N-dipropyl-p-isopropylaniline

4-isopropyl-2,6-dinitro-N,N-dipropylaniline

4-(1-methylethyl)-2,6-dinitro-N,N-dipropylbenzenamine

Other Names: PAARLAN, EL-179

Chemical Abstracts Service (CAS) registery No.: 33820-53-0

EPA Shaughnessy No.: 100201

Molecular formula (and weight): $C_{15}H_{23}N_3O_4$ (309.4)

MANUFACTURING PROCESS 163.61-4

Information on Elanco's manufacturing process is reported (Elanco Products Co., 00002559 or 0002789) in the Appendix of Confidential Data.

The Agency does not consider the information given on the manufacturing process used by Elanco to be sufficiently detailed. Data and information are needed concerning the specific factors in the manufacturing process which affect the composition of the technical material; e.g., the composition of the starting materials and reaction solvents with information on their impurities, the reaction temperatures, and the side reactions. Data are also needed concerning the packaging materials, quality control measures, and other factors related to the composition and presence of unintentional ingredients in the formulated product.

DISCUSSION ON THE FORMATION OF UNINTENTIONAL INGREDIENTS 163.61-5

The Agency is concerned about the presence of impurities in pesticide products which have the potential for producing adverse human and environmental effects. Because such impurities are related to both the manufacturing and formulating process, a discussion is needed relating these processes to the composition of each isopropalin product proposed for registration. The discussion should indicate the product ingredients, and also the expected impurities and reaction products [secondary nitrosamines are occasionally found in dinitroaniline herbicides of the isopropalin type]. The discussion should be based on established chemical theory.

Although such a discussion has not been submitted, analytical methodology and quantitative composition data have been submitted for the registered formulation, PAARLAN Emulsifiable Concentrate. Similar data have been submitted for technical isopropalin. The composition data reported, located in the Confidential Appendix show significant amounts of nitrosodipropylamine (NDPA) in samples of formulated isopropalin. Depending on the conditions of storage, such impurities may exceed 85 ppm (Bontoyan, et al., GS0005-002). See the topical discussion on Product Analytical Methods and Data, page 37.

DECLARATION AND CERTIFICATION OF INGREDIENT LIMITS 163.61-6

This section of the guidelines requires a commitment (certification) from the registrant that the ingredients and impurities of his product will be maintained within specified limits for as long as the product is offered for sale. For the product PAARLAN certification of upper and lower limits are required for the ingredients, active and inert; upper limits, for the impurities (including N-nitrosamines). Without submitting such certification, Elanco has submitted much of the data needed to set such limits; i.e., storage stability data for the isopropalin formulation and also quantitative data for isopropalin and its related compounds and associated impurities.

The only registered isopropalin product, PAARLAN E.C., is an emulsifiable concentrate of 68.6% [6.0 pounds per gallon), inerts 31.4%,] with directions for use on tobacco. Therefore, isopropalin formulations that can be registered under this standard must be similar emulsifiable concentrates of isopropalin and limited, in accordance with the latest accepted label, to use on tobacco. Any producer proposing the registration of another type of isopropalin product may petition the Agency to amend this Standard.

PRODUCT ANALYTICAL METHODS AND DATA 163.61-7

The Guidelines require that the appropriate analytical methodology be used for determining the composition of the product; i.e., the submitted methods must meet the Agency's requirement for accuracy and precision and must be capable of determining whether active ingredient(s) and impurities fall within the limits certified for the product. These methods are also expected to be suitable for determining the composition of samples of isopropalin products that are collected in Federal-State regulatory programs and other investigations conducted by the Agency.

Methods for isopropalin:

A collaborative study (Decker, et al. 05001253) conducted by the Association of Official Analytical Chemists (AOAC) has established acceptable methods, Gas-Liquid Chromatography (GLC) and spectrophotometric ultra-violet (UV), for determining isopropalin in both the technical grade material and formulations. Additional procedures (Matsunaga, et al., 05001069; Johnson, et al., 05001063), suitable as check methods, have been submitted.

Methods for the unintentional ingredients and impurities:

Confidential company data (Elanco Products Co., 00002789 and 00002559) provides procedures suitable for determining the related compounds of isopropalin; another Elanco method (GS0005-003) effectively determines the nitrosamine impurities of isopropalin products.

Studies published in 1978 (Cohen, et al., 05006328) and 1979 (Bontoyan, et al GS0005-002), using Elanco methodology for determining the nitrosamine impurities in isopropalin products, provide data on the nitrosodipropylamine (NDPA) of investigational samples collected by the Agency. In a following section titled the "Quantitative Data on the Composition of Isopropalin Products", page 38 the data on the composition of isopropalin products are summarized.

Identifying spectra and data related to the analysis of isopropalin:

Ultraviolet, infrared, and NMR-spectral data have been reported for isopropalin (Elanco Products Co., 00002789; Keszthelyi, et al., 05001065); also a study was reported (Keszthelyi, et al., 05001066) on the reduction potential of similar dinitroaniline compounds and the halfwave potential of isopropalin in buffered solutions of aqueous ethanol.

Quantitative Data on the Composition of Isopropalin Products:

The submitted composition data for isopropalin per-se and its related compounds in both the technical material and the formulated product are adequate.

Concerning the impurities in the formulated product, additional data are needed. A study published in 1978 (Cohen, et al. 05006328) gave values of 85(87-84) ppm and 46(54-39) ppm of N-nitroso-di-n-propylamine in marketed samples of isopropalin collected by the Agency. Duplicate samples were analyzed by two laboratories. Co-author Bontoyan also reported his results of 46(54-39) ppm NPDA in a separate paper (Bontoyan, et al., GS0005-002). Confidential data from the manufacturer filed with the Agency in June 1978 (Elanco Products Co., GS0005-001) indicated that levels of NDPA in formulated isopropalin products, analyzed six months after formulation, were much lower than the minimum published NDPA figures. Further, data submitted in February, 1980 (Elanco Products Co., GS0005-003) indicated that the NDPA content of new lots of PAARLAN, E.C. were less than one part per million. Chromatograms of the analyses were not provided. No information has been provided indicating that the manufacturing process has been changed to minimize the production of NDPA. If this is the case, then details on the new manufacturing process must be supplied. No information has been provided on NDPA formation over time. Aliquots must be taken at different time intervals from a single batch of technical isopropalin and the formulated product and analyzed for N-nitrosamines. Therefore on the basis of the data that have been submitted, isopropalin's contamination problem cannot be defined. NDPA levels may be due to contamination of the starting material, occur as an impurity in the manufacturing process, or the NDPA may be formed during storage.

Additional data are needed concerning the NDPA and possibly other nitrosamines that may be present in formulated products of isopropalin. That is, quantitative data are needed for such impurities in the product shortly after formulation and after a storage period of one year, in accordance with the guideline requirements, Section 163.61-8(c)(12). Although confidential composition data have been submitted (Eli Lilly and Co., 00002590; Decker, et al., 00002591) for isopropalin formulation samples following one year of storage, this study does not provide data on the impurities of nitrosamines.

The unpublished data concerning the NDPA impurity in products of isopropalin are reported in the "Appendix of Confidential Data."

PHYSICAL AND CHEMICAL PROPERTIES OF THE TECHNICAL MATERIAL

For every pesticide product, the Proposed Guidelines require data for both the technical chemical (pesticide) used to formulate the product and data concerning certain physical and chemical properties of the formulated product. These data are needed to identify and assess the hazards associated with the use pattern of the product.

The data available indicate technical isopropalin (approximately 99% purity) has physical and chemical properties as follows:

Color: yellow-orange, (Johnson, et al., 05001063)

Odor: There are no data for the technical material and data must be provided.

Melting point: Isopropalin is a liquid at room temperature, therefore melting point data are not required.

Solubility: The following data are for the technical chemical at room temperature (Elanco Products Co., 00002559, and 00002789).

Solvent	Grams of isopropalin per 100 mls of solvent
water pH 3	9×10^{-6}
pH 7	11×10^{-6}
pH 11	13×10^{-6}
acetone	>100
acetonitrile	>100
benzene	>100
chloroform	>100
hexane	>100
methanol	>100

Stability: The effects of small amounts of impurities (e.g., alkali, acids and metallic ions) on the stability of isopropalin (the technical chemical) are not reported. These data must be provided by the applicant. Isopropalin is light sensitive (Johnson, et al., 05001063) and decomposes at elevated temperatures (Elanco Products Co., 00002789).

Octanol-water partition coefficient: There are no data for the technical material and data must be provided.

Physical State: Liquid, (Weber, et al., 05001096).

Specific gravity: There are no data for the technical material and data must be provided.

Boiling point: There are no data for the technical material and data must be provided.

Vapor Pressure: For the technical material the following values have been reported:

3.0×10^{-5} mm Hg at 24.6°C. (Johnson, et al., 05001063)

1.45×10^{-5} mm Hg at 25°C. (Weber, et al., 05001096)

pH: The technical material is weakly basic (Weber, et al., 05001096)

PHYSICAL AND CHEMICAL PROPERTIES-OF THE EMULSIFIABLE CONCENTRATE 163.61-8

For every pesticide product, the Proposed Guidelines require data for certain physical and chemical properties, in order to determine the necessary precautionary labeling.

A small amount of data are available on the physical and chemical properties of isopropalin's emulsifiable concentrate. PAARLAN E.C. contains six pounds of isopropalin per gallon.

Color: There are no data for the formulation. Data must be provided by the applicant.

Odor: There are no data for the formulation. Data must be provided by the applicant.

Physical state: Liquid, Elanco's Confidential Statement of Formula, Registration Jacket # 1471-79.

Specific gravity: There are no data for the emulsifiable concentrate. Data must be provided by the applicant.

pH: There are no data for the emulsifiable concentrate and it must be provided by the applicant.

Storage stability: The submitted data (Decker, et al., 00002591) indicate that the formulated product is stable at 25°C over a one year period, but the data on impurities (nitrosamines) that developed during storage, in accordance with Section 163.61-8(c)(12), were not reported. The data on the nitrosamine content of samples of the formulated product following a six months storage period together with other data on the impurities associated with the isopropalin manufacturing process are summarized in the "Appendix of Confidential Data."

Flammability: There are no data for the emulsifiable concentrate and data must be provided by the applicant.

Oxidizing, reduction potential: There are no data for the emulsifiable concentrate and data must be provided by the applicant.

Explosiveness: There are no data for the emulsifiable concentrate and data must be provided by the applicant.

Miscibility: There are no data for the emulsifiable concentrate and data must be provided by the applicant.

Viscosity: There are no data for the emulsifiable concentrate and data must be provided.

Corrosion characteristics: There are no data for the emulsifiable concentrate and data must be provided.

Dielectric constant: Data are not needed for this property because the registered use pattern for the emulsifiable concentrate indicates that the herbicide is not used around high voltage lines and transformer stations.

IV. ENVIRONMENTAL FATE

Use Profile for Isopropalin

Isopropalin, produced by Elanco Products Company, a division of Eli Lilly and Company, is used on tobacco land as a selective, soil-incorporated, preplant or pretransplant herbicide. It is used to control annual grasses such as barnyardgrass, crabgrass, foxtails and ryegrass; and broadleaf weeds such as lambquarters, pigweed, and purslane (See Table 1). Approximately 400,000 to 500,000 pounds of the active ingredient are produced per year.[1/]

The product PAARLAN® contains 68.6% isopropalin (2,6-dinitro-N,N-dipropylcumidine), containing 6 lb. a.i. per gallon. It is used on soil intended for flue-cured, burley, Maryland, and dark tobacco. Isopropalin is also registered in combination with other pesticides, nematocides and dry bulk fertilizers. The pesticide products registered for use with isopropalin are Diazinon , (diazinon, Ciba-Geigy), Di-Syston , (disulfoton, Chemagro), Mo Cap , (prophos, Mobil Chemical).

Flue-cured tobacco, the most extensively grown type of tobacco, is a principal constituent of domestic blended cigarettes and the chief type of tobacco exported. It is also used in smoking mixtures, and for chewing tobacco. This type of tobacco is grown in southern Virginia, middle and eastern North Carolina, eastern South Carolina, southeastern Georgia, and northern Florida. Flue-cured tobacco is best suited to soil which is well-drained and of low natural fertility, with good capacity to hold moisture. Soils in these categories are found in the Piedmont and Coastal Plain regions of the southeastern U.S. These soils are underlain by different mixtures of gravel, loose sand, sandy clay, and sometimes clay subsoil.

Rotation of flue-cured tobacco and other tobacco varieties with other crops is a common cultural practice. Crops commonly rotated with tobacco are corn, soybeans, and peanuts. Cover crops such as small grains, legumes and grasses are also rotated with tobacco. Data on isopropalin residues in rotational crops must be provided by the registrant or a rotational crop restriction must be added to the present label, for specific information please see pages 12, 23 and 61.

The following major tobacco-producing states reported treating 47% of their total acreage of flue-cured tobacco (187,500 acres) with isopropalin: North Carolina (91,000), South Carolina (37,000), Georgia (37,000), Virginia (22,000), and Florida (500). Application is by tractor-mounted or tractor-drawn sprayers with nozzles located 18 inches above the ground at rates of 1.5 to 2.0 lb A.I./acre. The pesticide is then incorporated immediately after application. The label for PAARLAN states that the product can be applied and incorporated up to 5 weeks before planting or transplanting at the rates of 2 pints (1.5 lb A.I./acre) on coarse and medium-textured soils to 2 2/3 pints (approximately 2 lb A.I./acre) on fine-textured soils.

[1/] No confidential business information has been used to arrive at this EPA estimate of production volume.

Table 1. Weeds Controlled by Isopropalin.[2]

Grasses Controlled

Large Crabgrass
Small Crabgrass(Smooth crabgrass)
Barnyardgrass (Watergrass)
Green Foxtail (Bottlegrass, Robust purple Robust white, Giant robust green)
Giant Foxtail
Yellow Foxtail
Ryegrass, annual (Italian ryegrass, Ryegrass)
Goosegrass (Silver crabgrass, Silvergrass, Wiregrass, Yardgrass)
Johnsongrass (Seedling only)
Field Sandbur
Fall Panicum(Spreading panicgrass)
Texas Panicum(Buffalograss, Colorado grass)
Crowfootgrass

Broadleaf Weeds Controlled

Spiny amaranth
Prostrate pigweed
Redroot Pigweed (Carelessweed, Rough pigweed)
Common Lambsquarters
Common Purslane
Carpetweed
Florida pusley, (Florida purslane, Mexican clover pusley)
Poorjoe

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[2] Isopropalin kills weed seeds as they germinate. Isopropalin will not control established weeds. Also it will not control certain resistant weeds such as cocklebur, velvetleaf, ragweed, jimsonweed, Venice mallow, and nutsedge (from PAARLAN, E.C. label).

Burley tobacco is used in manufacturing cigarette blends, pipe-smoking mixtures, and chewing tobacco. The leading states for burley production are Kentucky, Tennessee, North Carolina, Ohio, Indiana, and Virginia. Burley tobacco is grown principally on silt loam soils of limestone origin. These soils often lack good drainage and must be drained by ditching or underground tile. Isopropalin is used very little in the growth of burley tobacco. In Tennessee and Kentucky, which produced over 50% of the burley tobacco in 1979, Tennessee reported only about 1,500 lb of isopropalin being used at a rate of 1.5 lb/acre on 1,000 acres of burley tobacco, while Kentucky reported that the isopropalin product was the least used of several herbicides used as preplant herbicides.

The PAARLAN label states that burley tobacco fields are to be treated at a rate of 2 pints per acre on all recommended soil textures. After application the product must be incorporated into the soil within eight hours. Planting or transplanting may be done the same day as application or up to five weeks after application. Tobacco may be planted the same day as application of the product, but after application and incorporation is completed.

Dark, air-cured tobacco is grown in Tennessee and small areas of Virginia, and Kentucky. The variety used in Virginia is grown on sandy loam with a rather tight clay subsoil. Others are grown on relatively heavy silt loams that contain a high percentage of clay and silt. Dark tobacco is used for export or in the domestic manufacture of chewing and smoking tobacco. There is no information on the use of isopropalin on dark tobacco.

There is no information on the use of isopropalin on Maryland tobacco. This is a new use added to the label in November 1980. The label states that PAARLAN can be used on Maryland tobacco before transplanting at rates of 2 pints per acre for all soil types.

DISCIPLINARY REVIEW

Environmental Fate Profile

Isopropalin may be photodegraded and can volatilize from soil surfaces. Preliminary data indicated that isopropalin may not leach under field conditions and may be adsorbed to soil, at least to silt loam. Isopropalin is degraded in soil to at least 12 metabolites, modifications of the parent compound occurring on the alkyl side chains or nitro groups. None of the identified metabolites appeared to accumulate in soils, and ultimate incorporation into soil humic and fulvic fractions was indicated. Microorganisms play a significant, but undefined, role in isopropalin degradation. Under field use conditions, isopropalin's half-life is less than two months in soils with a high sand content; sand, loamy sand, and sandy loam soils. Isopropalin persists in clay soil, with a half-life of about eight months. Isopropalin can dissipate in sandy clay loam, medium silt loam and loam soils as rapidly as it does in sandy soils. However, isopropalin can also persist in the latter two soil types. Persistence can be great enough, at least in silt loam and clay soils, that isopropalin accumulation may occur after several annual applications.

Unidentified radiolabeled residues were found in mature wheat, seed and straw planted as a rotational crop about four months after soil treatment of the recommended application rate. Radiolabled residues accumulated moderately in sunfish exposed to 14^{C} isopropalin in a flow-through exposure system. Subsequent depuration was rapid

Exposure Profile[1/] -Emulsifiable Concentrate Formulation

The potential for exposure of humans, livestock or wildlife to isopropalin outside the application site is low because the herbicide is incorporated into the soil after application. The greatest exposure is likely to result during dilution, mixing, and application operations, but no quantitative data are available to estimate the degree of such exposure. A potential for dermal and eye exposure exists due to splashing during the dilution and mixing processes. Although isopropalin has a relatively low vapor pressure (3.0×10^{-5} mm Hg at 24.6°C), rapid volatilization from soil surfaces has been reported (29% volatilized within 24 hours at 33% soil moisture at 30°C). This suggests a potential for inhalational exposure during application, especially before soil incorporation is completed.

Preliminary leaching data indicate that human exposure via drinking water contamination may not be a problem. Neither [^{14}C]isopropalin nor its metabolites were eluted from aerobically aged (30 days) sandy loam soil leached with the equivalent of 0.5 acre-inch of water for 45 days; all of the radioactivity remained in the top 2 inches of a 30 cm column. Field studies indicate that isopropalin usually remains in the 0-3 inch soil layer. Octanol/water partition data are lacking but moderate bioaccumulation occurs in sunfish (up to 1600X in edible tissues) with rapid depuration.

1/ The exposure profile is a qualitative assessment which is an extrapolation from little, if any, actual exposure data.

The principal region of exposure to isopropalin is the Southeastern United States, and especially Georgia, North Carolina, South Carolina and Virginia. These states are the major producers of flue-cured tobacco, which accounts for the principal use of the herbicide.

Data Requirements

Environmental Fate data requirements for the registration of an Integrated-Formulation-System Product are listed on pages 19-23. Specific data requirements are from the Proposed Guidelines for the Registration of Pesticides in the United States, (43 FR 29712, July 10, 1978).

Labeling Requirements

Do not use in a crop rotation program for food or feed crops.

TOPICAL DISCUSSIONS

Isopropalin has outdoor, terrestrial use on nonfood crops. This requires that certain information be submitted in order to assess the possible adverse effects of isopropalin on the environment.

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines for Registering Pesticides' of July 10, 1978 (43 FR 29712) which explain the minimum data that the Agency usually requires in order to adequately assess a pesticide's Environmental Fate. Where no section number is listed, a minimum requirement has not been set for such information.

PHYSICO-CHEMICAL-TRANSFORMATION-163.62-7

Hydrolysis 163.62-7(b)

Hydrolysis data are required to support the registration of each manufacturing-use product and of each formulated end-use product intended for terrestrial, forestry, aquatic, and aquatic impact use patterns, including products directly discharged into the aquatic environment, indirectly discharged into wastewater treatment systems, or used as treatments in a wastewater system. Soil incorporated pesticides may come into contact with water, (by exposure to soil moisture from precipitation; field run-off to rivers, ponds or other bodies of water; or by discharge into wastewater systems from manufacturing or formulating facilities). No data have been submitted on isopropalin's chemical reactions with water and the resultant products. Isopropalin's ability to persist in a body of water is unknown. Therefore, since no hydrolysis data are available for isopropalin, data specified in Section 163.62-7(b) are needed to assess the hydrolysis properties of isopropalin.

Photodegradation 163.62-7(c)

Photodegradation studies are required to support the registration of each formulated end-use product intended for terrestrial (except greenhouse and domestic outdoor), aquatic, and forestry use, and for any aquatic impact use which results in direct discharges into the aquatic environment. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Four photolysis studies were reviewed and two were considered valid. Parochetti and Dec (05001076) measured the effect of 7 days' exposure to direct mid-July sunlight on the photodecomposition of ring-labeled [^{14}C] isopropalin applied at 1 ppm to thin-layer plates of Hagerstown clay loam soil. The calculated photodecomposition loss for isopropalin under these conditions was 8% of the initial sample activity. Five unidentified compounds were detected by thin-layer chromatography-autoradiography of soil extracts. Kennedy and Talbert (05001267) demonstrated that the loss of isopropalin (in methanol, unspecified purity) applied at 1 ppm to a silt loam soil averaged 19% after 24 hours' exposure to UV light (about 310 nm), compared with a 5% loss of an identical sample in the dark at the same temperature (45^{o}C).

These studies demonstrate that photodegradation of isopropalin can occur, but no data are available on the rate of photodegradation and the nature of the photodegradation products. Since isopropalin is used as a soil incorporated herbicide, degradation studies on soil will not be needed. However, since the potential exists for isopropalin to reach aquatic system (by runoff), data specified in Section 163.62-7(c) are needed to determine the effect of light on isopropalin in water.

METABOLISM-163.62-8

Data on metabolism are required to determine the nature and availability of pesticide residues to rotational crops and to help in the assessment of potential disposal and reentry hazards.

Soil 163.62-8(b,c)

An aerobic laboratory soil metabolism study is required to support registration of each formulated end-use product intended for terrestrial, or forestry use. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

An anaerobic soil metabolism study is required to support the registration of each formulated end-use product intended for field or vegetable crop use. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Four metabolism studies were reviewed, all of which were considered valid. Two studies (00002473 and 05001260) were combined into a single review because they contained original data from the same experiment. Golab and Althaus (00002473 and 05001260) removed the top 3 inches of a clay soil from field plots and mixed it with uniformly ring-labeled [^{14}C] isopropalin to yield 1.5 and 3.0 lb a.i./A. The treated soils were returned to the field, vegetable crops were planted and rotated with wheat, and the fate of the radioactivity and isopropalin in the top 6 inches of the soil was assessed over a three-year period. There was no difference in the rate of dissipation or distribution of radioactivity in the soil with respect to the different application rates. An increasing amount of radioactivity became unextractable with time, reaching a plateau of 25-30% of the original amount by 15 months. Based on extractable isopropalin, a half-life of about eight months can be estimated. About 25, 19, and 7% of the applied isopropalin was extractable 15, 24, and 36 months, respectively, after treatment. A detailed analysis of 15-month samples yielded the following results. About 50% of the unextractable radioactivity was in the humic acid fraction, another 30% was in the fulvic acid fraction. Twelve radiolabeled metabolites were identified (Table 1), none of which exceeded 4% of the applied isopropalin. About 20% of the applied radioactivity was unaccountable with uptake indicated in samples of the treated and rotational crops. Partial degradation pathways for isopropalin in field soil were proposed based on the above results (Figure 1, page 50).

Table 1. Products of isopropalin degradation in field soil.

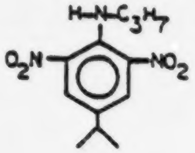
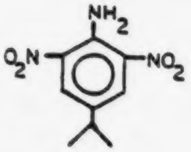
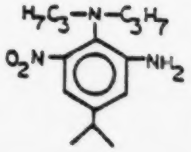
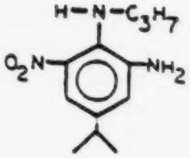
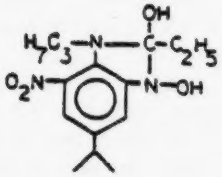
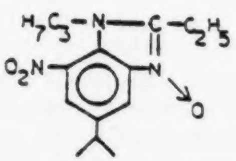
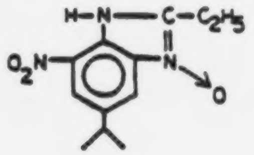
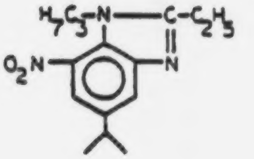
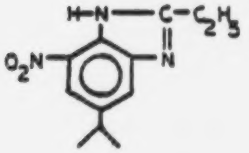
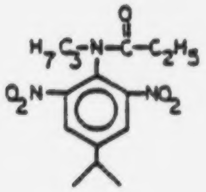
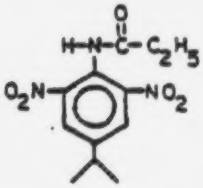
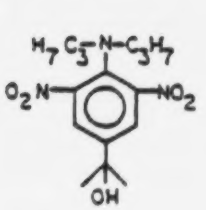
Compound number	Structure	Compound
I-2 182		2,6-dinitro-N-propylcumidine
I-3 185		2,6-dinitrocumidine
I-4 183		4-isopropyl-6-nitro-N^1,N^1-dipropyl-o-phenylenediamine
I-5 184		4-isopropyl-6-nitro-N^1-propyl-o-phenylenediamine
I-10 169		2-ethyl-2,3-dihydroxy-5-isopropyl-7-nitro-1-propyl-benzimidazoline
I-11 ---		2-ethyl-5-isopropyl-7-nitro-1-propyl-benzimidazole-3-oxide

Table 1. Products of isopropalin degradation in field soil (continued).

Compound number	Structure	Compound
I-12 170		2-ethyl-5-isopropyl-7-nitrobenzimidazole-3-oxide
I-13 188		2-ethyl-5-isopropyl-7-nitro-1-propylbenzimidazole
I-14 189		2-ethyl-5-isopropyl-7-nitrobenzimidazole
I-17 195		4'-isopropyl-2',6'-dinitro-N-propylpropionanilide
I-18 196		4'-isopropyl-2',6'-dinitropropionanilide
I-36 162		α,α-dimethyl-3,5-dinitro-4-dipropylaminobenzyl alcohol

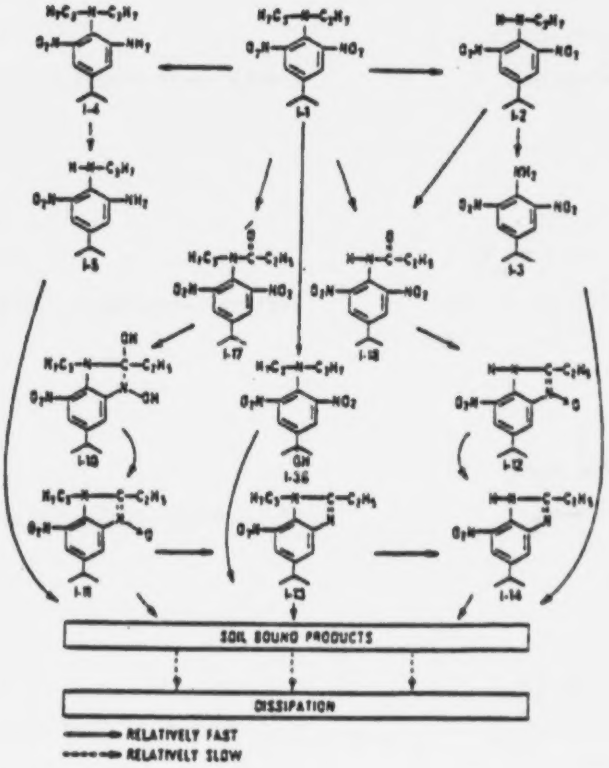

I-1
I-2
I-3
I-4
I-5
I-10
I-11
I-12
I-13
I-14
I-17
I-18
I-36
SOIL BOUND PRODUCTS
DISSIPATION
RELATIVELY FAST
RELATIVELY SLOW

Figure 1. Proposed degradation pathways for isopropalin in field soil. I-1, isopropalin; other chemical names listed in Table 1.

Gingerich and Zimdahl (05001257) determined the rates of degradation of isopropalin (unspecified formulation) added to a loam soil at 8 ppm and incubated under aerobic (2% moisture) and anaerobic (submerged) conditions. The calculated half-lives under aerobic conditions were 3.5 months at 30° and 13.3 months at 15°C. Its calculated anaerobic half-lives were about 5 and 20 days at 30° and 15°C, respectively; thus, anaerobic degradation was approximately 20 times faster than aerobic degradation. No metabolites were sought in this study, and no attempt was made to differentiate between hydrolysis and metabolism. Calculated activation energies suggested that degradation was due primarily to chemical processes.

Isopropalin (in acetone, unspecified purity) was added at 4 ppm to a silty clay loam, which was then submerged in one inch of tapwater and incubated at 84°F (Elanco Products Company, 00002814). Only 4% of the applied amount was detectable after 36 days, and the half-life under these conditions was about ten days. In this study, the time at which anaerobiosis was established was not determined. The mononitro derivative of isopropalin, Compound 183 (Table 1), was detected in large amounts (at least 20-30% of the applied isopropalin) at days 11 and 15 but declined substantially thereafter. The precise values for the metabolite could not be assessed due to poor recovery data.

In summary, isopropalin in soil is degraded more slowly under aerobic conditions than under anaerobic conditions. The initial stages of aerobic isopropalin degradation in soil may occur via several routes, but the metabolism of isopropalin beyond any of the products illustrated in Table 1 is not demonstrated in the available data. None of the metabolites in Figure 1 and Table 1 appear to accumulate under aerobic conditions. Data are not available to establish an anaerobic degradation pathway. A major metabolite found under semiaerobic conditions is the mononitro derivative of isopropalin. Available data provide information in that some of the metabolites are identifed, however, aerobic soil metabolism studies are needed to establish patterns of formation and decline of metabolic products. Residues comprising more than 10% of the initial application or 0.01 ppm, whichever is greater, should be identified. Data specified in Section 163.62-8(b) and Section 163.62-8(c) are needed to determine the differences in patterns of metabolism between aerobic and anaerobic soil conditions.

Aquatic 163.62-8(d,e)

No data are required on the aquatic metabolism of isopropalin since it is not used in an aquatic environment.

MICROBIOLOGICAL

Data on the effects of microbes on pesticide degradation and the effects of pesticides on microbes are required to support the registration of all formulated products intended for the following uses: terrestrial noncrop, tree fruit/nut crop field/vegetable crop, aquatic food crop and noncrops, forest, and direct discharge aquatic impact. These data are also required to support the registration of each manufacturing-use product which legally could be used to make such a formulated product.

Effects of Microbes on Pesticides

One study on the ability of microorganisms to metabolize isopropalin was reviewed and considered valid. Golab (00002600) reported that isopropalin was undetectable 24 hours after addition, as an unspecified formulation at 10 ppm, to artificial rumen fluid incubated under anaerobic conditions (temperature not given). No degradation could be demonstrated in sterilized preparations of rumen fluid. Isopropalin was degraded slowly in submerged samples of nonsterile soil, in which 27% of the applied sample was detectable at 48 days. No degradation of isopropalin was observed for 27 days in soil samples kept under sterile conditions. Neither the microorganisms responsible for isopropalin degradation nor its degradation products were characterized in the course of this study.

The requirement for the submission of above data is currently being reserved. Consequently the absence of acceptable data does not constitute a data gap.

Effects of Pesticides on Microbes

One study on the effects of isopropalin on microorganisms was reviewed and considered valid. Probst (00002601) reported that the growth of 35 species of bacteria and fungi in culture was not inhibited by isopropalin (added as an acetone solution) at 100 ug/ml or less and that the growth of six species of protozoa and algae was not inhibited by isopropalin at 40 ug/ml or less. However, the highest concentration of isopropalin used in this study exceeded its water solubility (0.11 ug/ml) by up to a thousandfold. Although the formulation of isopropalin used was not specified, the details of the dilution procedures suggested that an analytical standard was used. If so, most of the isopropalin in the agar medium was in an insoluble state. Therefore, it can be assumed only that isopropalin is truly nontoxic to these organisms when applied at concentrations equivalent to its water solubility. Additionally, several groups of soil-inhabiting bacteria were not represented in this study. Therefore, the results reported here must be regarded as preliminary.

The requirement for the submission of the above data is currently being reserved. Consequently the absence of acceptable data, does not constitute a data gap.

Activated Sludge

No data on the activated sludge metabolism of isopropalin are available. The requirement for the submission of these data is currently being reserved. Consequently the absence of acceptable data does not constitute a data gap.

MOBILITY 163.62-9

Data on mobility are required to determine pesticide residue movement in the environment.

Leaching 163.62-9(b)

Leaching data are required to support registration of each formulated end-use product intended for terrestrial noncrop, tree fruit/nut crop, aquatic, or forestry use or for any aquatic impact use resulting in direct discharges into the aquatic environment. Such data are also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Five leaching studies were submitted and all were considered valid. Holzer and Sieck (00002474) reported that neither isopropalin nor its metabolites could be eluted from a 30-cm column containing sandy loam soil treated with [^{14}C] isopropalin and aged aerobically for 30 days prior to leaching with the equivalent of 0.5 acre-inch of water for 45 days. All of the applied radioactivity remained in the top 2 inches of the column.

Barrentine (00002803 and 00002804), Humphreys (00002806), and Helmer and Thompson (00002805) used bioassays to determine that most of the isopropalin (technical or 1-6 lb/gal emulsifiable concentrate) applied to 30- or 20-cm columns containing silt clay loam and sandy soils remained in the top 2 inches of the columns after leaching with the equivalent of 6 acre-inches of water. In these studies, soil properties were sometimes incompletely reported, chemical identification and quantitation of residues were not made, the eluate was not analyzed and the columns were leached with relatively low volumes of water. Therefore, additional acceptable leaching studies on aged isopropalin, in accordance with the registration guidelines, are required. However, the requirement for the submission of these data is currently being reserved pending the receipt and evaluation of data on hydrolysis, photodegradation in water, aerobic and anaerobic soil metabolism, and rotational crops. Consequently, the absence of data does not constitute a data gap.

Volatility 163.62-9(c)

Laboratory volatility studies using nonradioisotopic analytical techniques are required to support the registration of all formulated products intended for greenhouse use or where re-entry intervals must be considered for field applicators. Four volatility studies were reviewed and three were considered valid. Kennedy and Talbert (05001267) noted that increasing moisture content increased the volatilization of isopropalin (unspecified formulation) from a silt loam soil under UV light at 30°C. At 1 and 14% soil moisture, 21% of the applied isopropalin (1 ppm) volatilized in 24 hours. At 26 and 33% soil moisture, 28 and 29%, respectively, of the applied isopropalin volatilized. Parochetti et al. (05001077) studied volatilization of isopropalin (unspecified formulation) from a sand soil for a three-hour period. Although the results are of limited use, the data demonstrate that increasing soil moisture increases volatilization from sand. Harvey (05001264) studied isopropalin (unspecified formulation) volatility with a bioassay in which vapors from isopropalin-treated agar (1.0 uM) inhibited foxtail millet growth to 14% of control growth.

Volatility data are only required for pesticides used in greenhouses or for the assessment of re-entry conditions in field applications. Volatility data for isopropalin are not required because no formulated product of isopropalin has yet been proposed for greenhouse use and isopropalin formulations as currently used do not warrant concern for re-entry situations. Although these data are not required, the results of these studies have been used in the preparation of the Exposure Profile, page 44.

Adsorption/Desorption 163.62-9(d)

A laboratory study using radioisotopic analytical techniques is required to support the registration of all formulated products intended for all terrestrial uses, terrestrial/aquatic (forest) uses, aquatic uses, and aquatic impact uses (if the pesticides are discharged directly into the aquatic environment). Such data are also required to support the registration of each manufacturing-use product which legally could be used to make an end-use product.

Two studies on the adsorption/desorption of isopropalin were reviewed and one was considered valid and the other invalid. Harvey (05001264) studied the adsorption of isopropalin (unspecified formulation) to a silt loam soil. The results indicated that isopropalin is strongly adsorbed to silt loam soil, but only one concentration was tested and therefore no adsorption isotherm was developed. The requirement for the submission of these data is currently being reserved pending receipt and evaluation of data on hydrolysis, photodegradation in water, aerobic and anaerobic soil metabolism and rotational crops. Consequently the absence of acceptable data does not constitute a data gap.

Water Dispersal 163.62-9(e)

No data on the water dispersal of isopropalin are required because isopropalin is not intended for use in the aquatic environment.

FIELD DISSIPATION 163.62-10

A field dissipation study under actual use conditions is required to support the registration of all manufacturing-use and formulated products intended for terrestrial (except greenhouse) uses, aquatic uses, and terrestrial/aquatic (forest) uses.

Terrestrial 163.62-10(b)

A terrestrial field dissipation study is required to support the registration of each formulated end-use product intended for terrestrial (except greenhouse) use. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Twenty-five terrestrial field dissipation studies were reviewed and 23 were considered valid and two invalid. Two studies (00002473 and 05001260) were combined into a single review because they contained original data from the same experiment. Golab and Althaus (00002473 and 05001260) removed the top 3 inches of a clay soil from field plots and mixed it with uniformly ring-labeled [^{14}C] isopropalin to yield 1.5 and 3.0 lb ai.i/A. The treated soils were returned to the field, vegetable crops were planted and rotated with wheat, and the fate of the radioactivity and isopropalin in the top 6 inches of soil was assessed over a three-year period. There was no difference in the rate of dissipation or distribution of radioactivity in the soil with respect to the different application rates. An increasing amount of radioactivity became unextractable with time, reaching a plateau of 25-30% of the original amount by 15 months. Total radioactivity in the soil had a half-life of 28 months. Only 57% of the orginal radioactivity had dissipated after 36 months. About 25, 19, and 7% of the applied isopropalin was extractable 15, 24, and 36 months, respectively, after treatment. Based on extractable isopropalin, a half-life of about 8 months can be estimated. A detailed analysis of 15-month samples yielded the following results. About 50 and 30% of the unextractable radioactivity was in the humic and fulvic acid fractions, respectively, of the soil. Twelve radiolabeled metabolites were identified (Table 1, page 48), none of which exceeded 4% of the applied isopropalin. About 20% of the applied radioactivity was unaccounted for after exhaustive analysis. Radioactivity was taken up into both treated and rotated crops. Partial degradation pathways for isopropalin in field soil were proposed based on the above results (Figure 1, page 50).

Eli Lilly and Company (00002597) and Webster (00002622) independently reported data on the same field dissipation experiment, in which a 6 lb/gal emulsifiable concentrate of isopropalin was incorporated into sandy loam soil. Three and seven percent of the added isopropalin was extracted from the 0-6 inch soil layer 160 days after treatment at 1.5 and 3.0 lb ai/A, respectively; the extraction method recovered only about 60% of the isopropalin. Accumulation and decline patterns for two metabolites, 2,6-dinitro-N-propylcumidine and 2,6-dinitrocumidine, were obtained. Maximum concentration of 2,6-dinitro-N-propylcumidine occurred 91-107 days after treatment, i.e., 0.085 and 0.12 ppm for the respective application rates. Maximum concentrations of 2,6-dinitrocumidine occurred 107 days after treatment; i.e., 0.017 and 0.02 ppm for the respective application rates. The metabolite residue levels declined by 25-50% of their maximum concentration by 160 days after treatment. Further data on this experiment are discussed below.

A number of field dissipation studies were performed by Elanco Products Company investigators, in which metabolites and levels of unextractable residues were not determined (Helmer et al., 00002621; Hobbs, 00002612; Humphreys, 00002614; Keaton, 00002615; Shoop and Strait, 00002611; Starker et al., 00002609; Steenwyk, 00002610; Watson, 00002613; Webster, 00002616). In all of these studies, only isopropalin residues were determined by using methods with proven reliable recovery rates (range, 75-100%). In all studies, a 6 lb/gal emulsifiable concentrate of isopropalin was applied at or near the recommended application rate. In all experiments but one, the herbicide was incorporated with a rotary hoe or tandem disc to depths of 2-3 and 3-4 inches, respectively. Various vegetable and grain crops, or tobacco, were planted immediately or shortly after isopropalin application in all experiments. In addition, fields were rotated to grain crops in half of the experiments. Only a few samples were taken at various times after application, and in some cases only one sample was taken. Thus, reliable half-life estimates or quantitative decline patterns cannot be deduced from the data. In addition, particle size analyses (PSA) and other soil characteristics were not provided in any of the studies.

The data from these studies, along with the data from the studies described above (Golab and Althaus, 00002473 and 05001260; Eli Lilly and Company, 00002597; Webster, 00002622) are condensed and summarized in Table 2.

A variety of sampling methods were used: simultaneous sampling of the 0-3 inch and 3-6 inch soil layers, single sampling of th 0-3 inch layer and single sampling of the 0-6 inch layer. For the purposes of Table 2, these data have been organized under the broader category of samples taken from the 0-6 inch layer, with those samples representing only the 0-3 inch soil layer indicated by a footnote.

On 42 occasions, samples were taken at the same time from both the 0-3 inch and the 3-6 inch soil layers. Analysis of these studies show that in 60% of these sampling events isopropalin residue levels are higher in the 0-3 inch layer than in the 3-6 inch layer. In the remaining 40%, residue levels were equal to or higher in the 3-6 inch layer than in the 0-3 inch soil layer. One-third of these values were generated by a study done in Orégon, (Starker, et al., 00002609).

Some data were available for the 6-12 inch soil layer. Isopropalin residues below 6 inches were undetectable or proportionately much lower than those residues found above 6 inches. The exception to this finding was the Oregon study (Starker, et al.; 00002609) which found that residue levels in 6-12 inch layer were higher than those in the 0-3 inch layer for two of the four application rates tested (sampled 11 months post application). With the exception of the Oregon study (Starker, et al.; 00002609), isopropalin residue levels in the 6-12 inch layers never exceeded more than 4% of the applied isopropalin. A possible explanation for the higher residue levels at lower soil depths in the Oregon study is that the field was plowed to a depth of 10-12 inches four months after treatment. No other plot in any of the other studies was plowed this deep.

Data in Table 2 are given for the recommended application rate when possible. Otherwise the data for the two application rates nearest the recommended rate were averaged. A trend is discernible for isopropalin degradation patterns as they relate to soil type. The data indicate that isopropalin disipates most rapidly in soils with a high sand content. Less than 10% of the applied isopropalin will be extractable from sand, loamy sand, and sandy loam soils one year after application. Isopropalin persists, but does not accumulate, in loam and clay soils, more so in the latter as was discussed in detail at the beginning of this topical discussion. In these types of soils, more than 10% of the applied isopropalin will be extractable one year after application. In a medium loam soil, 11% of the applied isopropalin was extracted at 15 months post-application, whereas in the clay soil 18% of the applied isopropalin was extracted from the 0-3 inch layer 24 months after application.

Table 2. Summary of Data From Field Dissipation Studies.

			Percent[a] of applied isopropalin in the 0-6 soil layer (unless otherwise noted) at various times after application							
State	Soil Type	Application rates (lb/A)	2-4 months	4.5-6 months	8-9 months	11-12.5 months	15 months	24 months	36 months	References
Florida	Sand	1 and 2	43	23	—	—	—	—	—	Humphreys (MRID 00002614)
Alabama	Loamy Sand	1 and 2	—	6[c]	—	6[c]	—	—	—	Webster (MRID 00002616)
North Carolina	Sandy Loam	1 and 3	—	—	—	5	—	—	—	Keaton (MRID 00002615)
Georgia	Sandy Loam	1.5	13	4	—	—	—	—	—	Webster (MRID 00002622 Eli Lilly and Co. (MRID 00002597)
Texas	Sandy Clay Loam	1 and 2	—	—	—	7	—	—	—	Hobbs (MRID 00002612
Mississippi	Medium Silt Loam	1.5	—	—	—	<2.6[d]	—	—	—	Watson (MRID 00002613
Oregon	Silt Loam	1 and 2	—	—	—	27	—	—	—	Starker et al (MRID 00002609
Indiana	Medium Loam	1.25 and 2.5	41[e]	—	25[e]	26[e]	11[e]	—	—	Helmer et al. (MRID 00002621)
California	Loam	1 and 2	70	—	33	—	—	—	—	Steenwyk (MRID 00002610)
Indiana	Loam	1.5	—	—	—	16	—	—	—	Shoop and Strait (MRID 00002611)
Indiana	Clay	1.5	65	67	—	40	23[e]	18[e]	6[e]	Golab and Althaus (MRID's 00002473 and 05001260)

[a] Expressed percentage values represent average of percentages obtained for two application rates where appropriate.

[b] In cases where the recommended application rate (1.5 lb/A) was not tested, the two application rates nearest the recommended rate are used here.

[c] Values obtained from two separate experiments in plots in the same field.

[d] Residues were not quantifiable.

[e] Only the 0-3 inch soil layer was sampled.

Only one study was performed on sandy clay loam soil, in which only 7% of the applied isopropalin was extracted 1 year after application. As no PSA or other soil properties were reported, and in light of the results with loam and clay soils, a conclusion regarding the behavior of isopropalin in sandy clay loam soil is not possible. It is possible that the sandy clay loam contained a high percentage of sand, in which case the results would fit the pattern observed for the sandy and sandy loam soils.

The results obtained for the two silt soil studies are contradictory. In one study (Mississippi), residues were not quantifiable 1 year after application, whereas in another study (Oregon), 27% of the applied isopropalin was extracted. Although there were differences in organic matter content, weather conditions, and types of crops planted, no conclusions can be drawn due to the lack of information on soil characteristics and pretreatment residue levels.

A study b/ ennedy and Talbert (005001267) demonstrates that isopropalin dissipates much more rapidly when it is surface applied rather than dissipates much more rapidly when it is surface applied rather than incorporated into the soil. Only 68, 43, and 24% of surface-applied isopropalin was recovered at 1, 3, and 7 days, respectively, after treatment with an unspecified formulation at 1.68 kg a.i./ha.

Four of the studies (Hobbs, 00002612; Shoop and Strait, 00002611; Starker et al., 00002609; Webster, 00002616) described above also contain limited data on residues in soil after a second application of isopropalin. In each case, the previous crops were harvested or plowed under prior to re-treatment and the planting of crops. The data are summarized in Table 3. In three cases (Oregon, Texas, and Georgia), the total amount of isopropalin residues in the combined soil layers sampled 11-12 months after the first treatment was 50% of the amount found 5-6 months after the second treatment, although the distributions of residues in the layers were proportionately different. These results indicate that the degradation of isopropalin applied the second time occurred at a faster rate than degradation after the first treatment because residues were still present at the time of the second application. Thus, if the rate of degradation was the same, the residue levels found 5-6 months after the second application would have been greater than twice those found 11-12 months after the first application. The rate of degradation after the second application to the Indiana loam soil was clearly much greater than that after the first application.

A number of studies were performed in which isopropalin residues were detected by bioassays that were incapable of quantifying residues. Isopropalin was detected in medium silt loam and medium loam soils 4 and 5 months, respectively, after application of a 6 lb/gal emulsifiable concentrate at 0.75 - 3.0 lb a.i./A (Watson, 00002798; Massey, 00002797), and in a silt loam soil 75 days, but not one year, after application of an unspecified formulation at 1.5 lb a.i./A (Harvey, 05002135). Residues were detected in unspecified soil types five and six months after application of 1 or 4 lb/gal emulsifiable concentrates at 0.5-3.0 lb a.i./A (Elanco Products Company, 00002800, 00003260, 00002801, and 00002802). Romanowski and Libik 05001083, reported that isopropalin had dissipated to negligible levels, as determined by bioassay, 4.5 and 3.5 months after application of

Table 3. Residues of Isopropalin in Fields Treated Twice.

Soil Type (State)	Application Rate (lb/A)	Sampled depth (inches)	Residues 11-12 Months After First Application (ppm)	Residues After Second Application (ppm) 1 month	5 months	6 months	References
Loam (Indiana)	1.5	0-3	0.23	0.54	—	0.12	Shoop and Strait (MRID 00002611)
		3-6	0.02	ND	—	0.02	
Silt loam (Oregon)	2.0	0-3	0.06	—	1.18	—	Starker et al. (MRID 00002609)
		3-6	0.53	—	0.24	—	
		6-12	0.18	—	0.04	—	
Sandy Clay loam (Texas)	2.0	0-3	0.09	—	—	0.23	Hobbs (MRID 00002612)
		3-6	0.03	—	—	0.01	
		6-12	ND	—	—	ND	
Loamy sand (Alabama)	2.0	0-3	0.02	—	0.08	—	Webster (MRID 00002616)
		3-6	0.05	—	0.02	—	
		6-12	0.02	—	<0.01	—	

an unspecified formulation of isopropalin at 1.12 kg/ha-3.36 kg/ha to silt loam and fine sand soils, respectively. Isopropalin (6 lb/gal emulsifiable concentrate) at 2.2 ppm persisted, as determined by bioassay, at least five and nine months in a silty clay loam soil under field and greenhouse conditions, respectively (Stoller and Wax, 05001088).

In summary, isopropalin will not accumulate in silt loam and sandy clay loam soils, and soils with a high sand content under normal field use conditions. Most of the applied isopropalin will remain in the 0-3 inch soil layer, and very little (<5% of the applied amount), if any, migration below the 6-inch depth will occur in most instances. Isopropalin will dissipate most rapidly from soils with a high sand content (sand, loamy sand, and sandy loam). Half-lives of less than 2 months can be expected in such soils, although the variable data do not allow for accurate estimates. Isopropalin tends to persist in loam and clay soils. The half-life of isopropalin in loam soils can be variable, ranging from about 2 to 6 months. The reasons for this variability cannot be discerned from the data. Isopropalin can dissipate as rapidly from a sandy clay loam soil as from a sandy soil. However, the available data from a single study are insufficient to determine if such a pattern is due to high sand and low clay content.

The behavior of isopropalin in silt loam soils cannot be predicted based on the available data, which are paradoxical. In such soils isopropalin may dissipate rapidly or persist in a manner similar to that for loam soils. Variables that may explain the observed behavior of isopropalin in silt loam and loam soils include soil characteristics, and the amount of soil bound residues. With only one exception, this information was not reported in the submitted studies. Isopropalin dissipates most slowly from a clay soil in which a half-life of about eight months was measured for extractable isopropalin. Unidentified unextractable residues also persist in clay soil, reaching a plateau of 30% of the applied isopropalin within 15 months after treatment. The available data generally satisfy the data requirements specified in Section 163.62-10(b).

Aquatic 163.62-10(c)

No data are required on the aquatic dissipation of isopropalin, because isopropalin is not intended for use in the aquatic environment.

Terrestrial Aquatic (Forest) 163.62-10(d)

No data are available and no data are required on the terrestrial/aquatic dissipation of isopropalin because isopropalin is not intended for use in a terrestrial/aquatic (forest) environment.

Aquatic Impact Uses 163.62-10(e)

No aquatic impact data are required because repeated direct or indirect discharge into the aquatic environment is not expected with normal use of this product.

Combinations and Tank Mixes 163.62-10(f)

A laboratory or field soil dissipation study, using the formulated product or the nonradiolabeled technical grade of each active ingredient, is required to support the registration of all formulated products intended for combinations and/or tank mixtures. This study shall compare the dissipation characteristics of each active ingredient of the mixture when applied to the soil as a mixture with the separate dissipation characteristics of each active ingredient in soil when applied individually.

Isopropalin has been registered in combination with other pesticides and nematocides. Those products registered for use with isopropalin are Diazinon , (diazinon, Ciba-Geigy), Di-Syston®, (disulfoton, Chemagro), and MoCap® (prophos, Mobile Chemical). Data requirements for mixtures of active ingredients are being reserved.

Data requirements are applicable only to mixed active ingredients.

ACCUMULATION 163.62-11

Data on accumulation are required to determine the potential for isopropalin to enter the food web and to assess potential adverse effects on nontarget organisms indicated by rotational crops, irrigated crops and fish.

Rotational Crops 163.65-11(b)

Accumulation studies on rotational crops are required to support the registration of each formulated end-use product intended for field/vegetable or aquatic food or feed crop use and for use on any site on which it is reasonably forseeable that any food or feed crop may be produced after application of a pesticide. Such a study is also required to support the registration of each manufacturing-use product which legally could be used to make such an end-use product.

Six rotational crop studies were reviewed. One study was invalid and five were considered valid. Two of these studies (05001260 and 00002535) were combined into a single review because they contained original data for the same experiment.

Golab and Althaus (05001260) and Golab et al. (00002535) reported that isopropalin residues were undetectable in straw and grain of wheat planted in rotation with vegetable and tobacco crops at least 17 weeks after application of [^{14}C] isopropalin to clay soil at 1.5 and 3.0 lb a.i./A. Unidentified radiolabeled metabolites were present at 0.007 and 0.01 ppm in the grain, and at 0.16 and 0.36 ppm in the straw of one-year old wheat for the respective application rates, as calculated based on radioactivity. Immature (two-month old) wheat plants contained metabolites at 0.065-0.125 and 0.125-0.330 ppm for the respective application rates. Analysis of extracts eliminated 2,6-dinitro-N-propyl-cumidine, 2,6-dinitrocumidine, and 4-isopropyl-6-nitro-N'-N'-dipropyl-*o*-phenylene-diamine as possible metabolites.

Eli Lilly and Company (0002509) treated fields with isopropalin (Paarlan) at 1.5, 2 or 3 lb/A and planted 14 rotational crops 112-374 days later. Mature plants were harvested for analysis of isopropalin residues. No isopropalin residues were detected in barley heads and straw; cabbage; corncob and grain; lettuce; oat heads, straw, and grain; snap beans; sorghum grain; soybean seed; spinach; turnip roots and greens; radish roots; wheat straw; peanut meats; and sugar beet tops. Either no detectable residues or residues of <0.01 ppm were found in samples of wheat heads, sugar beet roots, and peanut shells.

Eli Lilly and Company (0002558) detected no residues in mature and immature pepper plants planted 50 days after application of an emulsifiable concentrate of isopropalin at 1-3 lb/A. The levels of residues in mature and immature pepper fruit samples were undetectable or less than 0.01 ppm, the latter values obtained only in two samples from plots treated at 2 lb/A. Similarly, isopropalin residues were undetectable, or at 0.01 ppm or less, in tobacco planted 35 days after application of a 6 lb/gal emulsifiable concentrate of isopropalin at 1.5-3 lb/A (Eli Lilly and Company, 00002507).

In summary, the data submitted does not supply adequate information on rotational crops. Unidentified radiolabeled residues are present in mature wheat seed and straw planted as a rotational crop four months after field treatment at the recommended application rate. Analyses made only for parent isopropalin demonstrated that isopropalin did not accumulate in 14 rotational crops planted 112-374 days after treatment.

Crops that can be rotated in connection with proposed use patterns must be identified. Data specified in Section 163.62-11(b) are needed to determine the uptake of isopropalin residues in rotational crops. Studies using radiolabeled isopropalin are required for representative leafy vegetable and root crops, and subsequent field studies may be required. The identification of residues found in small grains is required, along with other unsatisfied data requirements calling for radiolabeled or nonradiolabeled pesticide. Residues should be chemically identified.

If the registrant does not wish to have a rotational crop restriction on an isopropalin product one of the following must be done:

a) Supply environmental fate data supporting a rotation interval which does not result in a pesticide residue in the rotated crops; or

b) Obtain a tolerance for the nontarget crop (46 FR 3018) or

c) Obtain an exemption from a tolerance for the nontarget crop.

Irrigated Crops 163.62-11(c))

No data are required on the accumulation of isopropalin in irrigated crops because the use pattern indicates that crops would not be irrigated with water containing isopropalin.

Fish Accumulation 63.62-11(d)

(1) A fish accumulation study is required to support the registration of each formulated end-use product intended for outdoor use (except domestic outdoor), or aquatic impact uses resulting in direct discharge into aquatic environments, and for each manufacturing-use product that could be legally used to produce such a product, except when the criteria below are satisfied. Although isopropalin does not have aquatic uses, the potential remains for contamination of aquatic systems (by run-off).

(2) Fish accumulation data will normally not be required in situations where the registrant can offer evidence acceptable to the Agency showing that the applied pesticide and/or its principal degradation product(s):

(a) Will not reach water, or will not persist in water (i.e., a nominal half-life of four days or less); and

(b) Has physical properties suggesting a relatively low potential for accumulation (i.e., a nominal octanol/water partition coefficient less than 1000); or

(c) Does not accumulate in the organs and tissues of mammals or avian species.

(3) The Agency may consider the particular use pattern and the rate and frequency of application in making a decision to waive or maintain the data requirement (such as in cases where movement to water is obviously negligible or where frequent application counteracts a fast dissipation rate).

One fish accumulation study was reviewed and considered valid. Sleight (00002475) examined the accumulation of isopropalin (technical) in edible tissues of bluegill sunfish, using a flow-through system. At an exposure level of 0.01 ppm over a 28-day period, maximum isopropalin residue levels of 2-4 ppm were found between three days postexposure and three days after the start of depuration. Residue levels decline thereafter to 0.61 and <0.04 ppm by 14 and 28 days, respectively, after depuration began. At an exposure level of 0.05 ppm over a 42-day period, maximum isopropalin residue levels of 25-40 ppm were found between 21 and 42 days post-exposure. Residue levels declined immediately after the start of depuration to an average of 9 ppm, 14 days later and to <1.07 ppm 28 days later. Residue levels in nonedible tissues were 8 and 113 ppm, 28 and 42 days after exposure (the only nonedible tissue sample days) to 0.01 and 0.05 ppm isopropalin, respectively. Mean residue levels in water were 50% of the nominal concentration. Thus, maximum bioaccumulation factors for edible tissue were 800 and 1,600 for the respective nominal concentrations, and these declined to <8 and <50 by the end of depuration. Respective bioaccumulation factors in nonedible tissue were 1,600 and 5,120 on the last days of exposure.

This study partially fulfills the guideline requirements for fish accumulation. The only additional data needed are on the identity of residues in whole body fish, edible tissue and viscera at suitable sampling intervals for a flow-through system.

The requirement for the submission of these data is currently being reserved pending the receipt and evaluation of data on hydrolysis, photodegradation in water, aerobic and anaerobic soil metabolism, and rotational crops. Consequently, the absence of acceptable data does not constitute a data gap.

V. RESIDUE CHEMISTRY

DISCIPLINARY REVIEW

Residue Chemistry Profile

Because the residues of isopropalin measured in tobacco at recommended application rates are quite low, less than 0.1 ppm, the Agency does not require data showing the metabolism of isopropalin on tobacco. Because these residues are low, residue profiles for isopropalin in the green tobacco, the cured tobacco, the tobacco smoke, or the pyrolysis products in the smoke are not required as specified in Section 163.64-1 of the Proposed Registration Guidelines 43 FR 29724, July 10, 1978.

Tolerance Reassessment

Neither a tolerance nor an exemption from a tolerance is required by the Agency for residue of pesticides in or on tobacco [Section 163.63-1].

Although isopropalin is no longer registered for use on food crops, tolerances have been established for negligible residues of the herbicide in or on peppers and tomatoes at 0.05 part per million, (40 CFR 180.313). Residue data submitted for tomatoes and peppers were evaluated and found adequate for establishment of a tolerance. Because isopropalin is currently not registered for use on tomatoes and peppers, a discussion of the data will not be presented in this chapter. For further discussion of tolerances please refer to the Regulatory Chapter, page 11.

Data Requirements

The proposed guidelines include the data requirements for pesticide residues in tobacco: 43 FR 29724, July 10, 1978. The residue chemistry data requirements are listed on page 24.

Data Gaps for Residue Chemistry

Although the residue chemistry studies needed to assess the recommended applications of PAARLAN E.C. to tobacco have been submitted, the Agency needs the raw data for the ^{14}C-residue study (Elanco Products Co., 00002506; Golab, et al., 05001260) to complete the review for this standard. It is also noted that residues of NDPA are not mentioned.

Required Labeling

For application to tobacco (burley, black, and flue-cured) to control annual grasses and broadleaf weeds:

Up to five weeks before planting or transplanting tobacco, the recommended application of PAARLAN E.C. should be soil incorporated.

TOPICAL DISCUSSIONS

Introduction

Since isopropalin is currently used in the cultivation of tobacco and no other crop, the discussion of its residues in crops will be limited to tobacco.

Neither a tolerance nor an exemption from a tolerance is required for pesticide residues in tobacco, but the Agency does require "Residue Profiles" in order to assess the human exposure to such residues when the tobacco is consumed. The required residue profiles [quantitative data for the pesticide per se and its metabolites] are dependent upon the total pesticide residues resulting in green tobacco by the recommended use. Total residues in the green tobacco equal to or greater than 0.1 ppm require a determination of the residue profile for the pesticide in the cured tobacco; total residues in the cured tobacco equal to or greater than 0.1 ppm require profile data for the smoke and perhaps additional toxicity studies. The proposed guidelines, Section 163.64-1(a)(b)(c), [43 FR 29696, July 10, 1978] explain the Agency's Special Data Requirements for pesticides used on tobacco.

USE PATTERN AND RESTRICTIONS

PAARLAN Emulsifiable Concentrate (Registration No. 1471-79), at this time the only registered isopropalin product, contains six pounds of the active ingredient per gallon (68.6%). On the basis of the isopropalin "Use Pattern Profile" applications of the product are limited to three types of tobacco: burley, flue-cured, and dark. The application (either broadcast or band), which must be soil incorporated to a depth of four to six inches, can be made up to five weeks before planting. A single application of the product is permitted per season. Isopropalin per se is applied at rates of from 1.5 to 2.0 pounds per acre.

Nature of the Isopropalin Residue in Tobacco

Because the total residues of isopropalin in green tobacco are shown to be less than 0.1 ppm, the Agency does not require data showing the metabolism of isopropalin by tobacco.

RESIDUE METHODS

Apart from the radiometric technique which was used to determine the total isopropalin residues (see paragraph below) the residues of isopropalin per se were acceptably determined in field tobacco by two of Elanco's GLC procedures, method numbers 5801590 and 5801588, for residue in crops.

RESIDUE DATA

Total Residues in Green Tobacco

The most relevant of the submitted studies (Elanco Products Co., 00002506 or Golab, et al., 05001260), was conducted with ^{14}C-ring labeled isopropalin. This study reports the total residues of isopropalin and its metabolites (based on total ^{14}C) in the bottom leaves of the mature tobacco plant (a flue cured cultivar). When treated at the minimum recommended rate of 1.5 pounds of the active ingredient (a.i.) per acre, these residues were 0.043(0.031-0.050) ppm. When treated at 1.5 times the maximum rate of 2.0 pounds of the a.i. per acre; i.e., with 3.0 pounds of the a.i. per acre, the total residues in the bottom leaves were 0.085(0.052-0.106) ppm; while total residues in the top leaves and stalk were respectively equal to or less than 0.071 ppm and 0.046 ppm.

Although the raw data were not submitted for this radiolabeled study, the reported isopropalin residues, as expected, were much higher than the residues determined in the tobacco field studies (Eli Lilly and Co., 00002477; Elanco, 00002554; Eli Lilly and Co., 00002507) conducted with nonradiolabeled isopropalin. In these tobacco field studies the maximum residue of isopropalin per se did not exceed 0.02 ppm; these residues were determined by Elanco's GLC procedures, method numbers 5801590 and 5801588 (Johnson, 00002793; Holzer, 00002795).

Also, noting the studies which were submitted in support of a negligible isopropalin tolerance of 0.05 ppm in or on peppers (Admundson, 00002557; Eli Lilly and Co., 00002558) and tomatoes (Golab, 00002786; Holzer, 00002790; Eli Lilly and Co., 00002620; Elanco Prouct Co., 00002816; Johnson, W.S., 00002593), it is apparent that the isopropalin residues in or on tobacco, as on peppers and tomatoes, would be quite low and definitely less than 0.1 ppm when treated with PAARLAN E.C. in accordance with the accepted labeling.

Residue Profiles for Isopropalin in Tobacco

The only ^{14}C-residue study conducted on tobacco indicates the total residue of isopropalin in green tobacco which would result from applications at the maximum recommended rate of 2.0 pounds of the a.i. per acre would not exceed approximately 0.073 ppm and would definitely be less than 0.1 ppm. Therefore, a residue profile for isopropalin and its metabolites is not required for tobacco either green or cured.

Total isopropalin residues, however, were reported for both the cured ^{14}C-tobacco and for the smoke from cigarettes prepared with the ^{14}C-tobacco. In this study, in which the treatment rate was 3.0 pounds of the a.i. per acre, the maximum residues in the cured tobacco leaf (bottom) were 0.523 ppm [0.430(0.523-0.355) ppm.]; and the total residues in the smoke, 0.116 ppm. Based on calculations from these data, the total residues of isopropalin in the tobacco treated at the maximum recommended rate of 2.0 pounds of the a.i. per acre would be approximately 0.35 ppm; and total residues in the smoke from cigarettes prepared with cured tobacco, less than 0.1 ppm (approximately 0.07 ppm).

Residue Profile for Isopropalin in Tobacco Smoke

Since the total residues of isopropalin in the tobacco is very low; i.e., less than 0.1 ppm, the Agency does not require a residue profile for isopropalin or its pyrolysis products in tobacco smoke.

Isopropalin Residues in Follow-up Tobacco

The proposed guidelines (Section 163.64-1) specify that pesticides applied to soil require supporting data from a study on follow-up tobacco. Submitted studies of this nature are reviewed in this standard as Environmental Fate data.

VI. ECOLOGICAL EFFECTS

DISCIPLINARY REVIEW

Ecological Effects Profile

Scientifically sound data on the toxicity of technical isopropalin to nontarget organisms is extremely scant. One study was available which was considered adequate to characterize the toxicity of isopropalin to a warmwater fish species. No data were available which were considered adequate to characterize its toxicity to other nontarget animal groups. The one warmwater fish study showed isopropalin, with an LC_{50} value of 200 (150-300) ppb, to be highly toxic to goldfish (*Carassius auratus*). No data were available to assess the toxicity of the formulated product, PAARLAN E.C., to wildlife.

Few studies on plants or microorganisms were presented with respect to the effects due to technical isopropalin. For two fungal species, 1×10^{-4} M is a no effect level. For tobacco, 1.5 lbs. a.i./A preplant incorporated was found to have no effect. Numerous studies were available noting the phytotoxic effects of an emulsifiable concentrate of isopropalin on various crops. A no observable effect level for tobacco was found to be between 3 to 4 lbs. a.i./A when applied as a preplant incorporated herbicide. Tomatoes and peppers were somewhat more sensitive with a 10% detrimental effect level between 0.75 and 4 lbs. a.i./A (PPI). Cotton and soybeans showed a 10% effect level at 1.5 to 2 lbs. a.i./A. Other crops had 10% detrimental effect levels ranging from 0.6 lbs. a.i./A for sorghum to 3 lbs. a.i./A for broccoli.

Ecological Effects Hazard Assessment

Due to the absence of appropriate Environmental Fate and nontarget toxicity data, an Ecological Effects Hazard Assessment cannot be made for either the technical or the formulated product.

Except for the effects on certain crops for which isopropalin is used and due to the absence of environmental fate information, an in-depth nontarget plant hazard assessment cannot be made at this time.

For the crops for which isopropalin is used as a preplant incorporated herbicide, there will be little or no detrimental effect at the usage rates as specified on the label.

Because the application methodology for isopropalin requires soil incorporation, there should be little or no effect on nontarget area plants.

Data Requirements

Data requirements are from the "Proposed Guidelines" of July 10, 1978, (43 CFR 29696) and November 3, 1980, (40 CFR 72948). Data requirements for an Integrated-Formulation System Product are on pages 25-30.

Labeling Requirements

In the absence of appropriate data, no new recommendations can be made with regard to the Environmental Hazard Statement of the present label. The revised label statement in the Regulatory Chapter, page 13, is considered adequate, until additional data are submitted.

TOPICAL DISCUSSIONS

Introduction

There is extreme variation in the sensitivity of non-human, non-target, organisms to pesticides. For example, among different species of fish more than a 30,000 fold difference in sensitivity in acute poisoning has been reported. In some cases, in order to achieve a "no effect" concentration for a species exposed to a chemical, it is necessary to reduce the concentration 20,000 fold from the level which causes "acute" effects. Since there is this potential for extreme sensitivity to wildlife species certain tests are required for all outdoor uses even if extremely minute amounts are expected in the environment. A number of species have been selected on the basis of sensitivity, habitat significance, and developed methodology by the scientific community. These recommendations have been incorporated into the proposed guidelines of July 10, 1978, (43 FR 29696), and November 3, 1980, (40 FR 72948).

Birds 163.71-1 and 163.71-2

Birds may be exposed to toxic amounts of isopropalin by ingesting contaminated soil organisms. Testing on birds is part of the first tier in the ecological effects testing scheme for pesticides with outdoor, terrestrial use.

There is insufficient information on isopropalin to characterize its toxicity to birds. Studies done by West and Worth (00002592A; 00002592B) were reviewed and found to be inadequate. In general, the testing parameters were not sufficiently defined. Also, in one study, the only treatment level (1g/kg) did not produce and LD_{50} value nor can one be estimated.

The following studies are required for isopropalin. An avian single - dose oral LD_{50} on one waterfowl (preferably the mallard) or an upland game bird (preferably the bobwhite quail or the ring-necked pheasant), according to the guidelines 163.71-1, is required. The species shall be the same as one of the two species selected for the avian dietary LC_{50} in 163.71-2. An avian dietary LC_{50} on two avian species, one species of waterfowl (preferably the mallard) and one species of upland game (preferably the bobwhite or the ring-necked) - 163.71-2. One of the two species selected for these studies must be the same species selected for the avian oral study required by 163.71-1.These test are required of products with an outdoor, terrestrial use and are part of the first tier in the ecological effects testing scheme.

Effects on Freshwater Fish 163.72-1

Studies done by Worth, Arthur and Anderson (00002472; and duplicates Eli Lilly, 00002787 and Elanco, 00002788) using the fathead minnow were inadequate. Another study in goldfish (West, et al., 00002592C) contained valid data on the technical material, however it does not satisfy the guideline reporting requirement. In general, the information provided with these studies was insufficent with regard to the test organism, protocol and statistical procedures used to analyze the data. Although the goldfish is not considered representative of warmwater fish species, the study does provide sufficient information to characterize isopropalin as highly toxic to warmwater fish. Additional data on this study may be submitted for further evaluation or another fish acute LC_{50} study must be initiated on one cold water (rainbow trout) and one warmwater (bluegill) species.

Effects on Freshwater Invertebrates 163.72-2

Data are required on invertebrates because they are important food sources for fish and other predators. Also, some species of invertebrates are economically significant. No documents have been received or evaluated under this topic. The following study is necessary in order to complete a hazard evaluation: Aquatic invertebrate LC_{50} (48-hour) on an immature invertebrate, preferably the daphnia, amphipod, stonefly or mayfly. This test is required of products with an outdoor, terrestrial use and are part of the first tier in the ecological effects testing scheme.

Terrestrial Macrophytes - Target Area Phytotoxicity 163.121-1

Requirements for efficacy data and phytotoxicity target data have been waived. The Agency's position is given in detail in the preamble to Proposed Subpart J, (45 FR 72950-72952).

Terrestrial Macrophytes - Nontarget Area Phytotoxicity (Seed Germination and Vegetative Vigor) 163.122-1.

The data submitted on terrestrial macrophytes are sufficient to assess the hazard of isopropalin to certain plants and are described according to species in this section. No additional data are required.

Based on available data the following is known about the toxicity of isopropalin to terrestrial macrophytes:

a. Isopropalin preplant incorporated expresses a 10% detrimental effect between 0.75 and 4 lbs. a.i./A on tomatoes. This effect level varies in response to edaphic and environmental conditions of the test locations.

The data supporting these conclusions are listed in the following table.

Species: Tomato

Formulation	EC_{10}	Author	Date	MRID
?EC	2 lb/A PPI	Ashton et al.	1970	00002575
6EC	<1 lb/A PPI	Wilson	1972	00002633
?	<1.2 lb/A PPI	Tisdell	1971	00002652
6EC	<.75 lb/A PPI	Putnam	1973	00002655
6EC	3 lb a.i./A PPI	Elanco	1969	00002695
6EC	4 lb a.i./A PPI	Lade	1969	00002696
6EC	4 lb a.i./A PPI	Massey	1969	00002697
6EC	3 lb a.i./A PPI	Massey	1969	00002698
6EC	2 lb a.i./A PPI	Massey	1969	00002699
6EC	3 lb a.i./A PPI	Massey	1969	00002700
6EC	1.5 lb a.i./A PPI	Elanco	1969	00002701
6EC	2 lb a.i./A PPI	Shoop	1969	00002702
6EC	0.75 lb a.i./A PPI	Elanco	1969	00002703
6EC	1 lb a.i./A PPI	Elanco	1969	00002704
6EC	3 lb a.i./A PPI	Pafford	1969	00002705
6EC	3 lb a.i./A PPI	Pafford	1969	00002706
6EC	1 lb a.i./A PPI	Warner	1969	00002707
6EC	1.5 lb a.i./A PPI	Steenwyk	1969	00002708
6EC	0.75 lb a.i./A PPI	Steenwyk	1969	00002709
6EC	1.5 lb a.i./A PPI	Steenwyk	1969	00002710
6EC	1.5 lb a.i./A PPI	Steenywk	1969	00002712
6EC	2 lb a.i./A PPI	Steenwyk	1969	00002713
6EC	4 lb a.i./A PPI	Cooper	1969	00002714
6EC	3 lb a.i./A PPI	Elanco	1969	00002715
6EC	1 lb a.i./A PPI	Elanco	1969	00002716
6EC	0.75 lb a.i./A PPI	Elanco	1969	00002717
6EC	1 lb a.i./A PPI	Elanco	1969	00002718
6EC	0.75 lb a.i./A PPI	Elanco	1969	00002719
6EC	0.75 lb a.i./A PPI	Elanco	1969	00002720
6EC	2 lb a.i./A PPI	Elanco	1969	00002721
6EC	1.5 lb a.i./A PPI	Elanco	1969	00002722
6EC	1 lb a.i./A PPI	Helmer	1969	00002724
6EC	2 lb a.i./A PPI	Helmer	1969	00002725
6EC	3 lb a.i./A PPI	Helmer	1969	00002726
6EC	0.75 lb a.i./A PPI	Elanco	1969	00002728
6EC	0.5 lb a.i./A PPI	Elanco	1968	00002729
6EC	1.5 lb a.i./A PPI	Elanco	1968	00002730
6EC	0.5 lb a.i./A PPI	Humphreys	1968	00002731
6EC	0.5 lb a.i./A PPI	Humphreys	1969	00002732
6EC	3 lb a.i./A PPI	Elanco	1969	00002733

Species: Tomato Cont.

Formulation	EC_{10}	Author	Date	MRID
6EC	3 lb a.i./A PPI	Massey	1969	00002734
6EC	0.75 lb a.i./A PPI	Webster	1969	00002735
6EC	2 lb a.i./A PPI	Keaton	1969	00002736
6EC	3 lb a.i./A PPI	Elanco	1969	00002737
6EC	4 lb a.i./A PPI	Helmer	1969	00002738
6EC	3 lb a.i./A PPI	Elanco	1969	00002739
6EC	3 lb a.i./A PPI	Elanco	1969	00002758
6EC	1 lb a.i./A PPI	Elanco	1969	00003257
Tech.(?)	2 lb a.i./A PPI	Fisher	1969	00002740
?EC	3 lb/A PPI	Hopen	1969	00002741
6EC	1.5 lb/A PPI	Greenfield	1969	00002742
6EC	1.5 lb/A PPI (transplanted)	Warner	1969	00002743
6EC	0.75 lb/A PPI (direct seeded)	Warner	1969	00002743
6EC	3 lb/A PPI	Monaco	1969	00002759
6EC	2 lb/A Post	Monaco	1969	00002759
6EC	<1 lb/A PPI (direct seeded)	Keaton	1970	00002773
6EC	1 lb/A PPI (direct seeded)	Steenwyk	1970	00002819
6EC	2 lb/A PPI (direct seeded)	Steenwyk	1970	00002820
6EC	1.5 lb/A PPI (direct seeded)	Steenwyk	1970	00002822
6EC	2 lb/A PPI (direct seeded)	Steenwyk	1970	00002823
?EC	<1.5 lb/A	Talbert	1974	00003252
6EC	2 lb/A PPI	Steenwyk	1970	00003262
6EC	1.5 lb/A PPI	Steenwyk	1970	00004151
?EC	1.5 lb/A PPI	Alban	1972	05001038
Tech.(?)	1.5 lb/A PPI	Anderson	1972	05001041
Tech.(?)	2.0 lb/A PPI	Orr	1974	05001074
?EC	1.95 ppm (soil)	Eshel	1972	05002134
?EC	0.13 ppm (water)	Eshel	1972	05002134

b. Isopropalin preplant incorporated expresses a 10% detrimental effect between 1.0 and 4.5 lbs/acre on peppers. The effect levels vary in response to edaphic and environmental conditions of the test sites.

The data supporting these conclusions are listed in the following table.

Species: Peppers

Formulation	EC_{10}	Author	Date	MRID
?EC	4 lb a.i./A PPI	Ashton	1970	00002575
?EC	3 lb/A PPI	Tweedy	1970	00002576
?EC	4.5 lb/A PPI	Univ. SWLA	1970	00002577
?EC	2 lb/A PPI (direct seeded)	Monaco	1969	00002579
?EC	3 lb/A PPI	Keaton	1971	00002580
6EC	2 lb/A PPI	Alban	1969	00002581
6EC	3 lb/A PPI	Ogle	1969	00002582
?EC	3 lb/A PPI	Tweedy	1969	00002587
6EC	3 lb/A PPI	Massey	1969	00002746
?EC	3 lb/A PPI	Hobbs	1969	00002583
?EC	3 lb/A PPI	Steenwyk	1969	00002584
?EC	3 lb a.i./A PPI	Elanco	1969	00002585
?EC	3 lb/A PPI	Massey	1969	00002756
?EC	3 lb/A PPI (Poor emergence)	Humphreys	1969	00002757
?EC	1 lb/A PPI	Keaton	1970	00002773
6EC	1 lb/A PPI	Humphreys	1976	00002775
6EC	3 lb/A PPI	Hobbs	1970	00003244
?EC	4 lb/A PPI	Hobbs	1970	00002562
?EC	1.5 lb/A PPI	Hobbs	1970	00002563
?EC	4.5 lb//A PPI	Warner	1970	00002564
?EC	2.5 lb/A PPI	Steenwyk	1970	00002565
?EC	3 lb/A PPI	Cooper	1970	00002566
?EC	4 ll 'A PPI	Humphreys	1970	00002567
?EC	3 lb/A PPI	Humphreys	1971	00002568
?EC	3 lb/A PPI	Hobbs	1969	00002744
?EC	2 lb/A PPI	Elanco	1969	00003242
?EC	4 lb/A PPI	Hobbs	1969	00003243
?EC	2 lb/A PPI	Hobbs	1970	00002570
?EC	2 lb/A PPI	Hobbs	1970	00002571
?EC	3 lb/A PPI	Hobbs	1970	00003245
?EC	2.5 lb/A PPI	Chamberlain	1969	00002747
?EC	2 lb/A PPI	Warner	1969	00002748
?EC	4 lb/A PPI	Cooper	1969	00002749
?EC	2 lb/A PPI	Elanco	1958	00003528
?EC	2 lb/A PPI	Humphreys	1970	00002572
?EC	1.5 lb/A PPI	Humphreys	1969	00002573
?EC	2 lb/A PPI	Humphreys	1970	00002574
?EC	1 lb/A PPI	Elanco	1968	00002750
?EC	2 lb/A PPI	Elanco	1968	00002752
?EC	1 lb/A PPI	Helmer	1969	00002753
?EC	1.19 ppm soil*	Eshel	1972	05002134
?EC	0.04 ppm water**	Eshel	1972	05002134

* Concentration in soil after incorporation treatment

** Concentration in hydroponic media

c. Isopropalin preplant incorporated expresses a no effect level about 1 lb/acre and a 10% effect level about 1.5 to 2 lbs/acre on cotton.

The data supporting these conclusions are listed in the following table.

Species: Cotton

Formulation	No-Effect Level	EC_{10}	Author	Date	MRID
6EC		1.5 lb/A PPI	Webster	1970	00002487
6EC		1.5 lb/A PPI	Webster	1970	00002488
6EC		2 lb/A PPI	Keaton	1972	00002491
6EC	1 lb/A PPI		Pafford	1970	00002774
?EC		>1.0 lb a.i/A	Overton	1972	05001075

d. Isopropalin incorporated expresses a no-effect level between 1.5 and 4.5 lb/acre and a 10% effect level at 2 lb/acre and above on soybeans. The differences are attributed to different environmental conditions during testing.

The data supporting these conclusions are listed in the following table.

Species: Soybeans

Formulation	No-Effect Level	EC_{10}	Author	Date	MRID
6EC		2 lb/A PPI	Keaton	1972	00002491
6EC	1.5 lb/A		Shoop	1970	00002770
?EC		<1.0 lb a.i./A PPI	Overton	1972	05001075
(?)	4.5 lb/A		Harvey	1973	05002135

e. The 10% detrimental level effect of preplant incorporated isopropalin on miscellaneous fruits and vegetable plants ranges from 0.6 lb/acre for sorghum to 3 lb/acre for broccoli.

The data supporting these conclusions are listed in the following table.

Miscellaneous Fruits and Vegetables

Species	Formulation	EC_{10}	Author	Date	MRID
Asparagus	?EC	<1 lb/A	Ashton	1970	00002575
Broccoli	?EC	3 lb/A	Ashton	1970	00002575
Cucumber	?EC	1.5 lb/A	Ashton	1970	00002575
Alfalfa	6EC	1 lb/A PPI	Massey	1970	00002679
Bushbeans	6EC	1.5 lb/A	Chamberlain	1976	00002771
Lima beans	?EC	1.0 lb a.i/A PPI	Overton	1972	05001075
Peas	?EC	<1.0 lb a.i./A PPI	Overton	1972	05001075
	?EC	1.5 lb/A	Harvey	1977	05001263
Sorghum	?EC	0.6 lbs/A PPI	Humphreys	1969	00002799
Oats	(?)	1.5 lb/A	Harvey	1973	05002135
Okra	?EC	<1.0 lb a.i./A PPI	Overton	1972	05001075
Eggplant	?EC	0.99 ppm soil*	Eshel	1972	05002134
	?EC	0.05 ppm water*	Eshel	1972	05002134

* Concentration in soil after incorporation treatment

** Concentration in hydroponic media

Aquatic Macrophytes and Algae 163.122-2

There are no data available to assess the effect of isopropalin on aquatic plants. Growth and reproduction studies of aquatic plants (*Lemna*, one marine diatom, one freshwater diatom, a green alga, and a blue-green alga) are required in order to complete a hazard evaluation.

ABBREVIATIONS USED IN TABLES FOR THE ECOLOGICAL EFFECTS CHAPTER:

a.i. = active ingredient (This term was used only when specifically stated in study.)

A = acre

EC = emulsifiable concentrate

6EC = emulsifiable concentrate which has a concentration of 6 pounds of isopropalin per gallon of end-use product (i.e. PAARLAN)

? = no information on formulation given

Tech. = technical product

Tech. (?) = technical product was most likely used, although it was not properly identified

PPI = preplant incorporation

Post = postemergence

EC_{10} = effective concentration which produces a 10% reduction in yield

VII. TOXICOLOGY

DISCIPLINARY REVIEW

TECHNICAL ISOPROPALIN

Toxicology Profile

Technical isopropalin has low acute oral toxicity with LD_{50} values in excess of 5000 mg/kg. Acute testing determined that at a single dose of 5000 mg/kg no mortality and very little toxicity was experienced by male or female rats. In addition, a single dose of 2000 mg/kg produced no mortality in mice, rabbits, dogs and chickens. These data suggest that isopropalin presents a very low level acute hazard to humans ingesting the technical material.

The acute dermal LD_{50} exceeds 2000 mg/kg and the primary eye irritation test showed slight conjunctival redness in treated animals eyes. These results indicate low dermal and eye toxicity. Neurotoxicity testing was not requested because the chemical structure is not related to substances that are known to cause acetylcholinesterase depression or delayed neurotoxicity.

In the category of subchronic testing, there is one acceptable 90-day rat study. The highest dose level used was 0.225% in the feed and no pathology was attributed to treatment.

No data on long term testing have been submitted on technical isopropalin. There is no information on the effects of chronic feeding, the oncogenic potential, or teratogenicity and reproductive effects of isopropalin.

The Agency has determined that certain testing will be required for isopropalin use on tobacco. Epidemiological studies have correlated cigarette smoking with cancer of the lungs, larynx, oral cavity, esophagus, pancreas, and bladder, (Wynder et al., 1957, Wynder and Bross 1961, Wynder, et al. 1973, Wynder and Goldsmith 1977, Wynder and Stellman 1977, Royal College of Physicians 1977, U.S. Dept. of Health Education and Welfare, 1971).

Also a correlation between tobacco chewing and cancer of the oral cavity, esophagus and possibly, cancer of the nasopharynx has been documented, (Moore et al., 1953, Wynder et al., 1957, Wynder and Bross 1961, Wynder and Hoffmann 1967, Jussawalla and Deshpande 1971, Staszewski 1974, U.S. Dept. of Health, Education and Welfare, 1971).

The components of tobacco smoke have been studied and a number of oncogenic agents have been identified, (Wynder and Hoffmann 1967, U.S. Dept. of Health Education and Welfare, 1971). In addition, tobacco-specific carcinogens have been identified in tobacco and tobacco smoke, specifically, N-nitrosonornicotine (NNN) and 4-(N-methyl-N-nitrosamine)-1-(3-pyridyl)-1-butanone (NNK), (Hecht et al. 1978a, Hecht et al., 1978b, Hecht et al., 1979, Hecht et al., 1980, and Hoffmann et al., 1980).

The Agency recognizes that the use of tobacco products is detrimental to the consumer and that the use of these products is voluntary. Even if pesticidal use were shown to enhance the formation of certain oncogenic agents it could not be considered the sole source of such agents. Therefore the following tests will not be required for isopropalin's use on tobacco: chronic feeding, oncogenicity, reproduction and metabolism. However teratogenicity and mutagenicity testing will be required in order to assess the potential effects to future generations of tobacco users.

N-Nitrosamine Contaminant of Technical Isopropalin

The technical material isopropalin is contaminated with N-nitroso-di-n-propylamine (NDPA). N-nitroso-di-n-propylamine has been shown to be a carcinogen by Druckery (1967)[1/], Reznik (1975)[1/], Pour (1973)[1/], and Dickhaus (1977)[1/]. Although Elanco has stated that the contaminaton level is less than one part per million, no data have been submitted to support this statement. Appropriate data must be submitted by the applicant to support contamination levels of less than one part per million or supply data necessary for a quantitative risk analysis.

Data Requirements

Data requirements for the registration of an isopropalin product are tabulated on pages 31-32. Listed beside each requirement is the section of the Proposed Guidelines of August 22, 1978, (43 FR 36336) that describes the type of data required.

Human and Domestic Animal Hazard Assessment

The data provided for the technical material of isopropalin is inadequate for a meaningful hazard assessment. The acute data indicate low toxicity and therefore suggest that the compound does not present an imminent hazard to those handling the product.

The lack of exposure data and data from long-term testing make estimation of the long-term hazard impossible.

Contamination with the nitrosamine contaminant, NDPA, may be a serious problem. Contamination levels need definition, storage stability confirmed and a quantitative estimation of the risk established if the level of contamination exceeds one part per million.

Required Labeling

Precautionary labeling of each product must correspond to the toxicity categories determined by five acute toxicity tests. Acceptable categories of acute toxicity and the corresponding required labeling appear in the Regulatory Chapter of this Standard (page 11).

[1/] These studies are listed as reference material in the bibliography.

TOPICAL DISCUSSIONS

Technical Material

Corresponding to each of the Topical Discussions listed below is the number of the section in the 'Proposed Guidelines' of August 22, 1978,(43 FR 37336) which explains the minimum data that the Agency usually requires in order to adequately assess a pesticide's toxicology. Where no section number is listed, a minimum requirement has not been set for such information. Also under each of the topics is a reference to the section in the 'Proposed Guidelines'.

The following topical discussions describe available toxicity data on technical isopropalin and state whether they are adequate for regulatory purposes.

ACUTE TESTING

Acute Oral Toxicity (163.81-1)

Acute testing using the technical material is required for integrated-formulation-system products. The minimum data requirement for testing acute oral toxicity is an LD_{50} as described in the guide-lines, preferably using the laboratory rat. One study in rats was reviewed, as well as studies in dogs, rabbits, mice, and chickens (Worth, et al., 00002472A, 00002472B, 00002472C, 00002472G, 00002472H). The rat study tested newborn, juvenile, and young adult groups, with adequate design for an LD_{50} determination. Acute oral toxicity studies in other species support the acute toxicity observed in the rat, and may be used in support of the rat data for regulatory purposes. The acute oral LD_{50} values for isopropalin in the young adult rat are greater than 5000 mg/kg for each sex. No mortality or symptoms of toxicity were observed in male and female mice, rabbits and dogs dosed with 2000 mg/kg. In chickens the LD_{50} is greater than 2000 mg/kg. The chemical belongs to oral toxicity category IV. These studies provide adequate information about the acute oral toxicity of technical isopropalin to meet the Agency's data requirements.

Acute Dermal Toxicity (163.81-2)

Acute testing using the technical material is required for integrated-formulation system products. The minimum testing needed on acute dermal toxicity is one test, preferably in the albino rabbit. One study was reviewed (Worth, et al., 00002472J). The data showed the LD_{50} exceeded 2000 mg/kg, therefore testing at other dose levels is not required. The study did not meet current guidelines for testing because an insufficient number of rabbits was used and a difference in response due to the sex of the animal was not tested. However, because of the low acute toxicity indicated by both the oral and dermal route, this test is accepted as adequate to justify labeling this product as dermal toxicity category III, but it is not sufficient to assign dermal toxicity category IV. Further testing of acute dermal toxicity is not required for the technical material.

Acute Inhalation Toxicity (163.81-3)

Data were not available for assessment of the acute inhalation toxicity of the technical isopropalin. This test is not required for the registration of an integrated-formulation system product.

Primary Eye Irritation (163.81-4)

The minimum testing to evaluate eye irritation potential is one test, in albino rabbits. If the test substance has a pH of 1-3 or 12-14, however, it will be judged corrosive, and an eye irritation test is not needed.

One study was evaluated (Worth, et al., 00002472 I). A slight conjunctival redness was observed in treated eyes. These results indicated that the product falls into toxicity category III according to 1975 regulations [40 CFR 162.10(h)(1)]. No observations were made after the seventh day, therefore it is not possible to recategorize this test according to criteria proposed in the National Academy of Sciences publication 1138. Since this test is not required for the registration of an integrated-formulation system product no further testing is required for this type of registration.

Acute Delayed Neurotoxicity (163.81-7)

An acute delayed neurotoxicity evaluation is not required because isopropalin is not expected to cause acetylcholinesterase depression, nor is its chemical structure related to that of substances that induce delayed neurotoxicity.

CHRONIC TESTING

Chronic Feeding (163.83-1)

No data were submitted and none are required for tobacco use. Refer to the Toxicology Profile, page 78, for additional information.

Oncogenicity (163.83-2)

No data were submitted and none are required for tobacco use. Refer to the Toxicology Profile, page 78, for additional information.

Teratology (163.83-3)

No teratogenicity data have been submitted. The minimum requirement for evaluating a pesticide for teratogenicity is testing in two mammalian species with the technical product. These data must be submitted by the applicant in order to assess the potential hazard to the offspring of tobacco-users.

Reproduction (163.83-4)

No data were submitted and none are required for tobacco use. Refer to the Toxicology Profile, page 78, for additional information.

Mutagenicity (163.84-1 through 4)

In order to assess the potential hazard to the offspring of tobacco-users mutagenicity data are required. No mutagenicity data were submitted for isopropalin. The following studies represent only the minimum requirements for data on the potential heritable effects of isopropalin:

1. A mammalian in vitro point mutation test.
2. A sensitive sub-mammalian point mutation test. (Bacteria, fungi, insect.)
3. A primary DNA damage test (i.e. sister chromatid exchange or unscheduled DNA synthesis).
4. A mammalian in vitro cytogenetics test. If this test suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these test systems and other toxicology disciplines have been considered, additional testing may be required to further characterize or quantify the potential genetic risks.

Although the Agency's mutagenic testing requirements are not final, the standards for these tests should be based on the principles set forth therein (43 FR 37388, August 22, 1978). Protocols and choices of test systems should be accompanied by a scientific rationale. Substitutions of test systems for those listed above will be considered after discussion with the Agency.

The requirements should be considered an interim guide and not final Agency policy. However, the Agency does consider the above testing scheme to be a reasonable minimum requirement.

Metabolism (163.85-1)

A general metabolism study is required to support the registration of each product which requires a chronic feeding study or an oncogenic study. Since neither of these studies are required for isopropalin this study is not required.

Emergency Treatment

No information on the prevention and treatment of isopropalin intoxication is available.

DISCIPLINARY REVIEW

Emulsifiable Concentrate Isopropalin

Toxicology Profile

An acute oral dose of the emulsifiable concentrate isopropalin which caused fifty percent mortality among the test animals, was 2.92 ± 0.15 ml/kg for males and 3.38 ± 0.19 ml/kg for females. No mortalilty was observed after a single dose of 2 ml/kg. Although this indicates that the emulsifiable concentrate is more toxic than the technical material it still presents a low level of acute hazard to humans ingesting the material.

An acute dermal toxicity test found no mortality with a single dose of 2 ml/kg. This indicates that the emulsifiable concentrate causes moderate dermal toxicity (category III) and necessitates appropriate labeling. A primary eye irritation test indicates that the emulsifiable concentrate is not well tolerated, causing corneal injury which was not reversed in seven days. The emulsifiable concentrate is classified as a Category I eye irritant according to the Agency's 1975 regulations [40 CFR 162.10(h)(1)].

No data were provided on acute inhalation and dermal sensitization.

N-Nitrosamine Contaminant of the Emulsifiable Concentrate

The emulsifiable concentrate of isopropalin is contaminated with N-nitroso-di-n-propylamine (NDPA). N-nitroso-di-n-propylamine has been shown to be a carcinogen by Druckery (1967)[2], Reznik (1975)[2], Pour (1973)[2], and Dickhaus (1977)[2]. Data must be provided by the applicant which would confirm that the source of contamination is the manufacturing-use product and that N-nitrosamines are not produced in the emulsifiable concentrate upon storage. Appropriate data must be supplied by the applicant for a quantitative risk assessment if contaminant values are greater than one part per million.

Data Requirements

Data requirements for an Integrated-Formulation System Product are tabulated on pages 31-32. Listed beside each requirement is the section of the Proposed Guidelines of August 22, 1978, (43 FR 37336) that describes the type of data required.

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[2] These studies are listed as reference material.

Human and Domestic Animal Hazard Assessment

The data provided for the formulated product of isopropalin is inadequate for a meaningful hazard assessment. The acute data indicate that the emulsifiable concentrate is more toxic than the manufacturing-use product. Although the formulation is currently classified as a Category I (high toxicity) eye irritant, the overall assessment is that the formulation is moderately toxic.

The lack of exposure data and data from long-term testing make estimation of the long-term hazard impossible.

Contamination with the nitrosamine contaminant, NDPA, may be a serious problem. Contamination levels need definition, storage stability confirmed and a quantitative estimation of risk established if the contaminant level exceeds one part per million.

Required Labeling

Precautionary labeling of each product must correspond to the toxicity categories determined by the five acute toxicity tests. Acceptable categories of acute toxicity and the corresponding required labeling appear in the Regulatory Chapter.

TOPICAL DISCUSSIONS

Emulsifiable Concentrate

Corresponding to each of the Topical Discussions listed below is the number of the section in the "Proposed Guidelines" of August 22, 1978, (43 FR 37336) which explains the minimum data that the Agency usually requires in order to adequately assess a pesticide's toxicology.

ACUTE TESTING

Acute Oral Toxicity (163.81-1)

All formulated products are required to have acute oral toxicity data submitted by the applicant. The minimum testing needed on acute oral toxicity is one test in the laboratory rat on each formulated emulsifiable concentrate product.

Full strength emulsifiable concentrate was tested in young adult rats of each sex (Worth, et al., 00002472H) using the same design as for technical isopropalin tests. This formulation was more toxic with LD_{50} values found to be 2.92 ± 0.15 ml/kg for males and 3.38 ± 0.19 ml/kg for the females, (the emulsifiable concentrate contained 720 mg of technical isopropalin per ml). These authors also tested chickens (Worth, et al., 00002472G) and observed longer lasting symptoms (anorexia and hypoactivity) in males dosed with the emulsifiable concentrate as compared with technical isopropalin; females were less affected. The LD_{50} remained greater than 2.0 ml/kg.

These studies also provide information about the acute oral toxicity of this formulated product adequate to justify labeling it as oral toxicity category III, but they are not sufficient to determine whether this product could be labeled as category IV. No further acute oral testing is required for this product.

Acute Dermal Toxicity (163.81-2)

All formulated products are required to have acute dermal toxicity data submitted by the applicant. The minimum testing needed on acute dermal toxicity is one test in the albino rabbit on each formulated emulsifiable concentrate product.

The full strength emulsifiable concentrate formulation was tested by the same authors using the same protocol (Worth, et al., 00002472J) as was used for the technical material. The single dose of 2.0 ml/kg (formulation containing 0.72 g isopropalin per ml) produced no mortality. The study did not meet current guidelines in other respects, such as sufficient numbers of rabbits per group and ability to test by sex. This test is accepted as adequate to justify labeling this product as dermal toxicity category III, but it not sufficient for designating a category IV toxicity rating. No further testing is required for assessing acute dermal toxicity.

Acute Inhalation Toxicity (163.81-3)

An acute inhalation toxicity test is required on an emulsifiable concentrate formulation if it causes a respirable vapor, or if 20% or more of the aerodynamic equivalent is composed of particles not larger than 10 microns.

One study was reviewed (Worth, et al., 00002472K). The study design was deficient in many important aspects with respect to current guidelines, and did not permit an estimation of the LC_{50}. The data available are not adequate to meet the Agency's requirements for regulating this formulation. Data must be submitted by the applicant.

Primary Eye Irritation (163.81-4)

All formulated products are required to have primary eye irritation data submitted by the applicant. The minimum testing needed to evaluate eye irritation potential is one test in albino rabbits on an emulsifiable concentrate formulated product. However, if the test substance has a pH of 1-3 or 12-14, it will be judged corrosive, and an eye irritation test is not needed.

One study was evaluated (Worth, et al., 00002472I). The emulsifiable concentrate was not well tolerated; corneal injury in two of the six treated rabbits had not healed after seven days. According to the Agency's 1975 regulations [40 CFR 162.10(h)(1)] this study classifies the emulsifiable concentrate as a Category I eye irritant. No observations were made after the seventh day, therefore it is not possible to recategorize this test according to criteria proposed by the National Academy of Sciences publication 1138. In this case several options may be exercised by the registrant: acceptance of category I classification according to the previously used criteria and revision of labeling; or submission of data from a new test which will permit recategorization under the new criteria. This recategorization may or may not result in a new toxicity category. The notice of availability of new testing guidelines for the primary eye irritation test was published on January 22, 1981 (46 FR 7075).

Primary Dermal Irritation (163.81-5)

All formulated products are required to have data on primary dermal irritation submitted by the applicant. The minimum testing needed to evaluate dermal irritation potential is one test, preferably in the albino rabbit, on each emulsifiable concentrate product. No data were available from tests meeting current guidelines, although limited observations were made during dermal toxicity tests (163.81-2). These observations are not adequate for regulatory purposes. Data must be provided by the applicant.

Dermal Sensitization (163.81-6)

All formulated products are required to have data on dermal sensitization submitted by the applicant. The minimum requirement for assessing dermal sensitization is an intradermal test on one mammalian species, preferably in the guinea pig, of the formulated product. No data were submitted and they must be provided by the applicant.

Guide to Use of This bibliography

1. Content of Bibliography. This bibliography contains citations of all the studies review by EPA in arriving at the positions and conclusions stated elsewhere in this standard. The bibliography is divided into 3 sections: (1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the standard, (2) citations examined and judged to be inappropriate for use in developing the standard, and (3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. Identification of Entries. The entries in this bibliography are sorted by author, data of the document, and title. Each entry bears, to the left of the citation proper, an eight-digit numeric identifier. This number is unique to te citations, and should be used at any time specific reference is required. This number is called the "Master Record Identifier", or "MRID". It is not related to the six digit "Accession Number" which has been used to identify volumes of submitted data; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. This is also to be used whenever a specific reference is needed.

4. Form of the Entry. In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. The bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no questions marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer reduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. This is the third element in the citation. In some cases it has been necessary for Agency bibliographers to create or ennhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to us in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission.

(1) Submission Date. Immediately following the word 'received' appears the date of the earlies known submission.

(2) Administrative Number. The next element, immediately following the word 'under', is the registration number, experimential permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase 'submitted by'. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification. The final element in the trailing parenthesis identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol 'CDL', standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
CASE GS0005 ISOPROPALIN

SECTION ONE: Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

PRODUCT CHEMISTRY

MRID	Citation
GS0005-002	Bontoyan, W.R.; Law.; Wright, D.P. (1979) Nitrosamines in agriculture and home-use pesticides. J. Agric. Food Chem. 27:631-635.
05006328	Cohen, S.Z.; Zweig, G.; Law, M.; Wright, D.; Bontoyan, W.R. (1978) Analytical determination of N -Nitroso compounds in pesticides by the United States Environmental Protection Agency --A preliminary study. Pages 333-342, in environmental aspects of N - Nitroso compounds. Washington, D.C.: Environmental Protection Agency, (IARC Scientific Publications, vol. 19).
00002591	Decker, O.D.; Frank, R. (1969) Agricultural Analytical Chemistry Method IN-APZ: Determination of EL-179 by GLC: 2,6-Dinitro-N, N- dipropylcumidine. Method dated November 18, 1969. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis Ind.; CDL:091664-B).
05001253	Decker, O.D.; Frank, R. (1974) Determination of the herbicide isopropalin in technical grade material and in formulations. Journal of the Association of Official Analytical Chemists 57(3):645-647.
00002559	Elanco Products Company (1969) Data Sheet: PAARLAN E.C. (Unpublished study received June 7, 1972 under 2F1278; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:095166-A.
00002789	Elanco Products Company (1969) EL-179. (Unpublished study received May 4, 1970 under 0F0968; prepared by Elanco Products Co.; Div. of Eli Lilly and Co.; CDL:093280-F).
GS0005-001	Elanco Products Company (1978) Response to the Federal Register notices of 09/29/77 and 12/29/77. Submission of data and methods used to determine the nitrosamine levels in PAARLAN E.C. [CDL].

PRODUCT CHEMISTRY

MRID	Citation
GS0005-003	Elanco Products Company (1980) Submission contains a copy of analytical procedure no. 5801677 for nitrosamines and the results of recent analyses on isopropalin.
00002590	Eli Lilly and Company (19??) EL-179 Formulations Storage Stability. (Unpublished study received April 26, 1971 under 1471-EX-321; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-A).
05001063	Johnson, W.S.; Decker, O.D. (1976) Isopropalin. Pages 169-279, In Analytical Methods for Pesticides and Plant Growth Regulators. Vol. 8. New York, N.Y.: Academic Press.
05001065	Keszthelyi, C.P.; Gardiner, H.L. (1976) Analytical spectroscopy environmentally important nitroaromatic compounds. Pages 59-64, In Proceedings of the Louisiana Academy of Sciences. Vol. XXXIX.
05001066	Keszthelyi, C.P.; Kenney, B.A.; Buras, P.J.; Southwick, L.M.; Willis, G.H. (1978) Coulometric study of the reduction of dinitroaniline compounds. Journal of the Electrochemical Society 125(5):714-717.
05001069	Matsunaga, A.K.; Yoneda, H. (1976) Determinacao dos herbicidas com grupo nitro por cromatografia de gas. [Determination of herbicidal nitro group compounds by gas chromatography] Arquivos do Instituto Biologico, Sao Paulo. [Archives of the Biological Institute of Sao Paulo]. 43(1/2):9-11.
05001096	Weber, J.B.; Monaco, T.J. (1972) Review of the chemical and properties of the substituted dinitroaniline herbicides. Pages 31-37, In Proceedings--Southern Weed Science Society. Vol. 25. Athens, Ga.: Southern Weed Science Society.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
CASE GS0005 ISOPROPALIN

SECTION ONE: Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

ENVIRONMENTAL FATE

MRID	Citation
00002803	Barrentine, J.L. 1969. Experiment No., JLB9-1: soil leaching data. (Unpublished study received April 30, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-C).
00002804	Barrentine, J.L. 1969. Experiment No. JLB9-2: soil leaching data. (Unpublished study received April 30, 1970, under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-P).
00003260	Elanco Products Company. 1968. Experiment No. GM8-36X: herbicidal efficacy data. (Unpublished study received April 30, 1970, under 0F0968; prepared by Elanco Products Co., Div of Eli Lilly and Co.; CDL:091661-K).
00002801	Elanco Products Company. 1968. Experiment No. GM8-41X: herbicidal efficacy data. (Unpublished study received April 30, 1970, under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-L).
00002814	Elanco Products Company. 1968? Introduction: degradation of EL-179. (Unpublished study received April 30, 1970, under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-AA).
00002800	Elanco Products Company. 1969. Experiment No. CDH8-32X: soil persistence data. (Unpublished study received April 30, 1970, under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-J).
00002802	Elanco Products Company. 1969. Experiment No. GM8-55X: herbicidal efficacy data. (Unpublished study received April 30, 1970, under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-M).

ENVIRONMENTAL FATE

MRID	Citation
00002597	Eli Lilly and Company. 1971. Degradation of isopropalin in soil. Includes method No. 5801606 dated March 12, 1971. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-H).
00002558	Eli Lilly and Company. 1971. EL-179--Peppers: EL-179 (2,6-dinitro-N,N-dipropylcumidine) as a preplant application for preemergence weed control in direct seeded and transplant peppers. Includes method No. 5801588 dated September 22, 1969; method No. 5801590 dated January 20, 1970. (Unpublished study received October 10, 1972, under 2F1278; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091815-B).
00002507	Eli Lilly and Company. 1971. Isopropalin--Tobacco: residue data on isopropalin (2,6-dinitro-N,N-dipropylcumidine) as a preplant application for preemergence weed control in transplant tobacco. Includes method No. 5801590 dated January 20, 1970 with modification. (Unpublished study received May 25, 1972, under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006399-C).
00002509	Eli Lilly and Company. 1973. Rotation crops--Paarlan: residue data on crops grown in rotation on Paarlan-treated fields. Includes method No. 5801590 dated January 17, 1974. (Unpublished study received September 17, 1974, under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co.; Indianapolis, Ind.; CDL:006925-A).
05001257	Gingerich, L.L., and R.L. Zimdahl. 1976. Soil persistence of isopropalin and oryzalin. Weed Sci. 24(4):431-434.
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00002473	Golab, T., and W.A. Althaus. 1971. Radiochemical studies with ^{14}C-isopropalin in soil. (Unpublished study received February 11, 1972 under 1471-79; prepared in cooperation with United States Testing Co., Inc.; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126281-A).

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MRID	Citation
05001260	Golab, T., and W.A. Althaus. 1975. Transformation of isopropalin in soil and plants. Weed Sc. 23(3):165-171.
00002535	Golab, T., W.A. Althaus, and M.E. Amundson. 1975? Uptake and distribution of ^{14}C-isopropalin in plants. (Unpublished study received on unknown date under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:221991-A).
05002135	Harvey, R.G. 1973. Field comparison of twelve dinitronaniline herbicides. Weed Sci. 21(6):512-516.
05001264	Harvey, R.G. 1974. Soil adsorption and volatility of dinitroaniline herbicides. Weed Sci. 22(2):120-124.
00002805	Helmer, J.D., and L.L. Thompson. 1969. Experiment No. WB9-56: soil leaching data. (Unpublished study received April 30, 1970, under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind; CDL:091661-Q).
00002621	Helmer, J.D.; W.J. Johnson, and T.W. Waldrep. 1970. Experiment No. WB(F)9-132: soil persistence data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli LilLy and Co., Indianapolis, Ind.; CDL:091664-AK).
00002612	Hobbs, C.D. 1970. Experiment No. CDH,0-15: herbicidal efficacy data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-W).
00002474	Holzer, F.J., and R.F. Sieck. 1972. EL-179: leaching study on degradation products. (Unpublished study received February 11, 1972, under 1471-79; prepared in cooperation with Purdue Univ., Agronomy Dept., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126281-C).
00002806	Humphreys, W.H. 1969. Experiment No. WHH9-27: soil leaching data. (Unpublished study received April 30, 1979, under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-R).

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MRID	Citation
00002614	Humphreys, W.H. 1970. Experiment No. WHH9,0-28: herbicidal efficacy data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-Y).
00002615	Keaton, J.A. 1970. Experiment No. JAK9,0-8: herbicidal efficacy data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-Z).
05001267	Kennedy, J.M., and R.E. Talbert. 1977. Comparative persistence of dinitroaniline type herbicides on the soil surface. Weed Sci. 25(5):373-381.
00002797	Massey, G.D. 1969. Experiment No. GDM9-19X: herbicidal efficacy data. (Unpublished study received April 30, 1970, under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-G).
05001076	Parochetti, J.V., and G.W. Dec, Jr. 1978. Photodecomposition of eleven dinitroaniline herbicides. Weed Sci. 26(2):153-156.
05001077	Parochetti, J.V., G.W. Dec, Jr., and G.W. Burt. 1976. Volatility of eleven dinitroaniline herbicides. Weed Sci. 24(6):529-532.
00002601	Probst, G.W. Undated. The effect of isopropalin on microorganisms. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:091664-L).
05001083	Romanowski, B.R., and A.W. Libik. 1978. Soil persistence of isopropalin, nitralin, and trifluralin. Weed Sci. 26(3):258-261.
05001084	Saghir, A.R.; Foy, C.L.; Hameed, K.M. (1972) Effect of herbicides on the germination of *Orobanche*. Pages 21-22, *In* Abstracts--1972 Meeting of the Weed Science Society of America; February 8-10, 1972, St. Louis, Missouri. Champaign, Ill.: Weed Science Society of America.
00002611	Shoop, G.J., and A. Strait. 1970. Experiment No. GJS9,0-12: soil persistence data. (Unpublished study received April 26, 1971, under 1471-EX-0-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-V).

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MRID	Citation
00002475	Sleight, R.H., III, 1972. Research Report: accumulation and persistence of ^{14}C-EL-179 residues by bluegill (*Lepomis marcrochirus*) continuously exposed to the chemical in water. (Unpublished study received February 11, 1972, under 1471-79; prepared by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126281-D).
00002609	Starker, C.H., H.E. Chamberlain, and D.I. McFee. 1970. Experiment No. CHS9,0-11: Herbicidal efficacy data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-T).
00002610	Steenwyk, P.I. 1970. Experiment No. PLS9,0-19: herbicidal efficacy data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-U).
05001088	Stoller, E.W., and L.M. Wax. 1977. Persistence and activity of dinitroaniline herbicides in soil. J. Environ. Qual. 6(2):124-127.
00002798	Watson, J.H. 1969. Experiment No. JHW9-21X: soil persistence data. (Unpublished study received April 30, 1970, under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-H).
00002613	Watson, J.H. 1970. Experiment No. JHW9,0-21: soil persistence: compound EL-179. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-X). (MRID 00002613).
00002622	Webster, H.L. 1970. Experiment No. HLW0-3: soil persistence data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Indianapolis, Ind.; CDL:091664-AL).
00002616	Webster, H.L. 1970. Experiment No. HLW9,0-16: herbicidal efficacy data. (Unpublished study received April 26, 1971, under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-AA).

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
CASE GS0005 ISOPROPALIN

SECTION ONE: Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

RESIDUE CHEMISTRY

MRID	Citation
00002506	Elanco Products Company (1971) Radiochemical Studies with 14C Isopropalin (Paarlan) on Tobacco. (Unpublished study received May 25, 1972 under 1471-79; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:006399-A).
00002554	Elanco Products Company (1969) Summary of Data: [EL-179]. Summary of studies 126687-C through 126687-R. Includes method No. 5801590 dated January 20, 1970. (Unpublished study received January 8, 1970 under 1471-EX-32; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:126687-P; 126639).
00002477	Eli Lilly and Company (1972) Isopropalin--Tobacco: Isopropalin as a Herbicide for Tobacco in Combination with Diazinon, DiSyston, and Prophos. Includes undated method entitled: The determination of Disyston, Diazinon and MoCap in tobacco plants; Method No. 5801590 dated January 20, 1970 entitled: Determination of compound EL-179 (2,6-Dinitro-N,N-dipropylcumidine) in agricultural crops. (Unpublished study received April 2, 1973 under 1471-79; prepared in cooperation with WARF Institute, Inc., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:101603-A).
00002507	Eli Lilly and Company (1971) Isopropalin--Tobacco: Residue Data on Isopropalin (2,6-Dinitro-N,N-dipropylcumidine) as a Preplant Application for Preemergence Weed Control in Transplant Tobacco. Includes method No. 5801590 dated January 20, 1970 with modification. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006399-C).
05001260	Golab, T.; Althaus, W.A. (1975) Transformation of isopropalin in soil and plants. Weed Science 23(3):165-171.
00002795	Holzer, F.J. (1969) Determination of EL-179 (4-Isopropyl-2,6-dinitro N,N-dipropylaniline) in Tomatoes and Peppers. Method No. 5801591 dated November 6, 1969. (Unpublished study received April 30, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-D).

RESIDUE CHEMISTRY

MRID	Citation
00002793	Johnson, W.S. (1969) Procedure No. 5801588: Determination of Compound EL-179 (4-Isopropyl-2,6-dinitro-N,N-dipropylaniline) in Agricultural Crops and Soil. Method dated September 22, 1969. (Unpublished study received April 30, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-E).

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REGISTRATION STANDARD BIBLIOGRAPHY
CASE GS0005 ISOPROPALIN

SECTION ONE: Citations Considered to be Part of the Data Base Supporting Registration Under the Standard

ECOLOGICAL EFFECTS

MRID	Citation
00002581	Alban, K. (1969) Research Data Record--Herbicide. (Unpublished study received June 6, 1972 under 2F1278; prepared by Ohio State Univ., Horticulture Dept., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AO).
05001038	Alban, E.K. (1972) Herbicide studies with processing tomatoes--1971. Pages 29-30, In Outdoor Vegetable Crops Research--1972. Wooster, Ohio: Ohio Agricultural Research and Development Center. (Research summary No. 57).
05001041	Anderson, J.L. (1972) The influence of temperature and moisture on tomato and weed responses to trifluralin and isopropalin. Pages 25-28, In Proceedings of the Western Society of Weed Science; March 14-16, 1972, Salt Lake City, Utah. Vol. 25. Boise, Idaho: Western Society of Weed Science.
00002575	Ashton, P.M.; Tisdell, T.; Neff, B. (1970) Evaluation of Herbicides for Vegetable Crops--1970. (Unpublished study received June 6, 1972 under 2F1278; prepared by Univ. of California--Davis, Dept. of Botany, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AG).
00002747	Chamberlain, H.E. (1969) Experiment No. HEC9-13: [Herbicidal Efficacy Data.] (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-BF).
00002771	Chamberlain, H.E. (1970) Experiment No. HEC0-25: [Herbicidal Efficacy Data.] (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-D).

ECOLOGICAL EFFECTS

MRID	Citation
00002749	Cooper, R.B. (1969) Experiment No. RBC9-7: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-BH).
00002714	Cooper, R.B. (1969) Experiment No. RBC9-8: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-V).
00002566	Cooper, R.B. (1970) Experiment No. RBC0-4: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-F).
00002716	Elanco Products Company (1968) Experiment No. CDH8-32: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-Y).
00002750	Elanco Products Company (1968) Experiment No. CDH8-33: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-BJ).
00002717	Elanco Products Company (1968) Experiment No. CDH8-38: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-Z).
00002718	Elanco Products Company (1968) Experiment No. GM8-7: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AA).
00002719	Elanco Products Company (1968) Experiment No. GM8-36: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AB).

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MRID	Citation
00002720	Elanco Products Company (1968) Expriment No. GM8-41: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AC).
00002722	Elanco Products Company (1968) Experiment No. GM8-58: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. Eli Lilly and Co.; CDL:092119-AE).
00002752	Elanco Products Company (1968?) Experiment No. GM8-63: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-BL).
00002729	Elanco Products Company (1968) Experiment No. IW8-46: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AL).
00002730	Elanco Products Company (1968) Experiment No. PS8-20: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AM).
00002695	Elanco Products Company (1969) Experiment No. CDH9-5: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-B).
00002758	Elanco Products Company (1969) Experiment No. CDH9-7: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-BS).
00003242	Elanco Products Company (1969) Experiment No. CDH9-8: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:09210[illegible]).
00002733	Elanco Products Products Company (1969) Experiment No. CDH9-15: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AP).

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MRID	Citation
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00002701	Elanco Products Company (1969) Experiment No. GJS9-10: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-H).
00002721	Elanco Products Company (1969) Experiment No. GM8-55: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AD).
00002703	Elanco Products Company (1969) Experiment No. JDH9-6: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-K).
00002704	Elanco Products Company (1969) Experiment No. JHW9-4: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-L).
00002728	Elanco Products Company (1969) Experiment No. IW8-3C: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-AK).
00003257	Elanco Products Company (1969) Experiment No. WB(F) 9-130: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-X).
00002739	Elanco Products Company (1969) Experiment No. WH8-50: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092110-AV).
00002715	Elanco Products Company (1969) Experiment No. WRA9-10: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co., CDL:092119-W).
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MRID	Citation
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05002134	Eshel, Y.; Katan, J. (1972) Effect of dinitroanilines on solanaceous vegetables and soil fungi. Weed Science 20(3):243-246.
00002740	Fischer, B.B.; May, D.M. (1969) Weed Control in Tomatoes Grown for Processing: Summary of 1969 Field Trials--Fresno County. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AW).
00002742	Greenfield Laboratories (1969) Research Data Record--Herbicide. (Unpublished study received April 9, 1970 under 0F0968; prepared in cooperation with Michigan State Univ., Horticulture Dept., Rutgers Univ., Weed Research, and Ohio State Univ., Horticulture Dept., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AY).
05002135	Harvey, R.G.. (1973) Field comparison of twelve dinitroaniline herbicides. Weed Science 21(6):512-516.
05001263	Harvey, R.G.; Jacques, G.I. (1977) Dinitroaniline herbicides for weed control in peas. Weed Science 25(3):256-259.
00002724	Helmer, J.D. (1969) Experiment No. JH8-68: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AG).
00002753	Helmer, J.D. (1969) Experiment No. JH8-69: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.;: CDL:092119-BN)
00002725	Helmer, J.D. (1969) Experiment No. JH8-70: [Herbicidal Efficacy Data]. (Unpublished study received April, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092119-AH)
00002726	Helmer, J.D. (1969) Experiment No. JH8-71: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.;: CDL:092119-A)

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MRID	Citation
00002738	Helmer, J.D. (1969) Experiment No. JH8-73: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092119-AU)
00002744	Hobbs, C.D. (1969) Experiment No. CDH9-6: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092119-EC)
00003243	Hobbs, C.D. (1969) Experiment No. CDH9-20: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-M)
00002583	Hobbs, C.D. (1970) Experiment No. CDH0-2: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-AQ)
00002562	Hobbs, C.D. (1970) Experiment No. CDH9-21: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-B)
00002563	Hobbs, C.D. (1970) Experiment No. CDH9-22: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-C)
00002570	Hobbs, C.D. (1970) Experiment No. CDH9-27: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-C)
00002571	Hobbs, C.D. (1970) Experiment No. CDH9-28: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-P)
00003244	Hobbs, C.D. (1970) Experiment No. CDH9-42: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-Q)

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MRID	Citations
00003245	Hobbs, C.D. (1970) Experiment No. CDH9-43: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-R)
00002741	Hopen, H.J. (1969) Tomato Weed Control Study: Downers Grove--1969 (Unpublished study including letter dated Oct. 30, 1969 from H.J. Hopen to George Shoop, received April 9, 1970 under 0F0968; prepared by Univ. of Illinois, Cooperative Extension Service, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AX)
00002731	Humphreys, W.H. (1968) Experiment No. WH8-1: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AN)
00002757	Humphreys, W.H. (1969) Experiment No. WH8-40: [Herbicidal Efficacy Data]. (Unpublished study received April, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-EB)
00002732	Humphreys, W.H. (1969) Experiment No. WH8-43: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AC)
00002799	Humphreys, W.H. (1969) Experiment No. WHH9-22: [Herbicidal Efficacy Data]. (Unpublished study received April 30, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-I)
00002573	Humphreys, W.H. (1969) Experiment No. WHH9-33: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-Y)
00002567	Humphreys, W.H. (1970) Experiment No. WHHO-4: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-G)
00002572	Humphreys, W.H. (1970) Experiment No. WHH9-31: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-X)

ECOLOGICAL EFFECTS

MRID	Citation
00002775	Humphreys, W.H. (1970) Experiment No. WHH9-35: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-H)
00002574	Humphreys, W.H. (1970) Experiment No. WHH9-43: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-Z)
00002568	Humphreys, W.H. (1971) Experiment No. WHH0-32: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-I)
00002736	Keaton, J.A. (1969) Experiment No. JAK9-24: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:092119-AS)
00002773	Keaton, J.A. (1970) Experiment No. JAK0-38: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:006401-F)
00002580	Keaton, J.A. (1971) University Research Report: January 11, 1970. (Unpublished study received June 6, 1972 under 2F1278; prepared in cooperation with North Carolina State Univ., Dept. of Horticultural Science, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.: CDL:092108-AN)
00002491	Keaton, J.A. (1969) Experiment No. JAK9,0,1-8 : [Herbicidal Efficacy Data]. (Unpublished study received Sep. 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:005589-N)
00002696	Lade, D.H. (1969) Experiment No. DH19-17: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-C)
00002697	Massey, G.D. (1969) Experiment No. GDM9-8: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-D)

ECOLOGICAL EFFECTS

MRID	Citation
00002698	Massey, G.D. (1969) Experiment No. GDM9-16: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-E)
00002734	Massey, G.D. (1969) Experiment No. GDM9-18: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AQ)
00002699	Massey, G.D. (1969) Experiment No. GDM9-19: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-E)
00002756	Massey, G.D. (1969) Experiment No. GDM9-20: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-EQ)
00002746	Massey, G.D. (1969) Experiment No. GDM9-31: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-EE)
00002700	Massey, G.D. (1969) Experiment No. GDM9-34: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-G)
00002769	Massey, G.D. (1970) Experiment No. GDM9-48: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-F)
000002579	Monaco, T.J. (1969) Evaluation of Herbicides in Direct-Seeded Peppers. (Unpublished study received Jun. 6, 1972 under 2F1278; prepared by North Carolina State Univ., Dept. of Horticultural Science, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:092108-AM)

ECOLOGICAL EFFECTS

MIRD	Citation
00002759	Monaco, T.J. (1969) Evaluation of Herbicides in Direct-Seeded Tomatoes. (Unpublished study including letter dated October 27, 1969 from J.W. Hooks to H.K. Bell, received April 9, 1970 under 0F0968; prepared by North Carolina State Univ., Coastal Plain Vegetable Research Station, Dept. of Horticultural Science, submitted by Elanco Proudcts Co., Div. of Eli Lilly and Co.,Indianapolis, Ind.; CDL: 092119-ET)
00002582	Ogle, W.I. (1970) An Evaluation of Herbicides for Vegetable Crops in 1970. Clemson: Clemson Univ. (Research series no. 133; p. 12 only; also In unpublished submission received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AP)
05001074	Orr, J.P.; Elmore, C.I. (1974) Canning tomato herbicide--varietal interaction trial. Pages 48-50, In Proceedings--Western Society of Weed Science. Vol. 27. Boise, Idaho: Western Society of Weed Science.
05001075	Overton, J.R.; Jeffery, L.S.; Brown, J.F.; Chambers, A.Y.; Swingle, H.D. (1972) Dinitroaniline evaluations in Tennessee over a three year period. Pages 73-87, In Proceedings--Southern Weed Science Society. Vol. 25. Athens, Ga.: Southern Weed Science Society.
00002705	Pafford, J.I. (1969) Experimennt No. JLP9-15: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-M)
00002706	Pafford, J.I. (1969) Experiment No. JLP9-17: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-N)
00002774	Pafford, J.I. (1970) Experiment No. JLP0-10: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-G)
00002655	Putnam, A. (1973) Weed Control in Seeded Tomatoes: Report No. 39375. (Unpublished study received May 6, 1976 under 3125-277; prepared by Michigan State Univ., submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CD: 224187-AI)

ECOLOGICAL EFFECTS

MIRD	Citation
0002537	Ridgeway, J.L (1975) Physical Stability of Paarlan with Liquid Fertilizers. (Unpublished study received September 29, 1975 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:223273-A)
00002702	Shoop, G.J. (1969) Experiment No. GJS9-11: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-I)
00002770	Shoop, G.J. (1970) Experiment No. GJS0-28: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-C)
00002708	Steenwyk, P.L. (1969) Experiment No. PLS9-6: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-P)
00002709	Steenwyk, P.L. (1969) Experiment No. PLS9-8: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-Q)
00002710	Steenwyk, P.L. (1969) Experiment No. PLS9-9: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-B)
00002712	Steenwyk, P.L. (1969) Experiment No. PLS9-14: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-T)
00002713	Steenwyk, P.L. (1969) Experiment No. PLS9-15: [Herbicidal Efficacy Data]. (Unpublished study received April, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-U)
00002819	Steenwyk, P.L. (1970) Experiment No. PLS0-9: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AF)
00002820	Steenwyk, P.L. (1970) Experiment No. PLS0-10: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AG)

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MRID	Citation
00004151	Steenwyk, P.L. (1970) Experiment No. PLSO-11: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AH)
00003262	Steenwyk, P.L. (1970) Experiment No. PLSO-12: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AI)
00002822	Steenwyk, P.L. (1970) Experiment No. PLSO-13: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AL)
00002584	Steenwyk, P.L. (1970) Experiment No. PLSO-14: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AR)
00002565	Steenwyk, P.L. (1970) Experiment No. PLSO-17: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-E)
00002823	Steenwyk, P.L. (1970) Experiment No. PLSO-19: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AM)
00003252	Talbert, R.E; Kennedy, J.M. (1974) Field Evaluation of Herbicides in Vegetable Crops, 1973. By Univ. of Arkansas, Depts. of Agronomy, Horticulture and Forestry. Fayetteville, Ark.: Univ. of Arkansas, Agricultural Experiment Station. (Mimeograph series 219; also in unpublished submission received May 6, 1976 under 3125-277; submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-BD)
00002652	Tisdell, T.; King, R. (1971) Nightshade Control in Tomatoes: Report No. 38866. (Unpublished study received May 6, 1976 under 3125-277; prepared by Univ. of California--Davis, Botany Dept., submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-AP)

ECOLOGICAL EFFECTS

MRID	Citation
00002587	Tweedy,? (1969) Research Report: An Evaluation of EL-179, Treflan and Dymid for Control of Weeds and to Establish Crop Injury on Peppers. (Unpublished study received June 6, 1972 under 2F1278; prepared by Southern Illinois Univ., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL: 092108-AX)
00002576	Tweedy, ? (1970) 1970 Research Report: An Evaluation of EL-179 Treflan, Dymid, and Planavin for Control of Weeds and to Establish Crop Injury on Peppers. (Unpublished study received June 6, 1972 under 2F1278; prepared by Southern Illinois Univ., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AI)
00002577	University of Southwestern Louisiana (1970) Summary of 1970 Pepper Herbicide Studies. (Unpublished study received June 6, 1972 under 2F1278; prepared by Dept. of Plant Industry, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AJ)
00002743	Warner, L.C. (1969) Experiment No LCW9-8: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Utah State Univ., Branch Experiment Station, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL;092119-BB)
00002707	Warner, L.C. (1969) Experiment No LCW9-13: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL;092119-C)
00002748	Warner, L.C. (1969) Experiment No LCW9-19: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL;092119-BG)
00002564	Warner, L.C. (1970) Experiment No LCW0-8: [Herbicidal Efficacy Data]. (Unpublished study received June 6, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL;092108-D)
00002735	Webster, H.I. (1969) Experiment No. HLW9-7: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092119-AR)

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MIRD	Citation
00002487	Webster, H.I. (1970) Experiment No. HLW9-3; [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-J)
00002488	Webster, H.I. (1970) Experiment No. HLW9-11; [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-K)
00002592C	West, H.C.; Worth, H.M., ed. (1970) Acute Effects of Compound 70379 in Quail, Ducks, and Goldfish. [96-hour LC_{50} in goldfish using the technical material and the emulsifiable concentrate, study numbers F-0-7-70 and F-0-8-70]. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-C)
00002633	Wilson, H.P. (1972) 1972 Weed Science Research Summary: Report No. 36933. (Unpublished study received May 6, 1976 under 3125-277; prepared by Virginia Truck and Ornamentals Research Station, Eastern Shore Branch, Dept. of Plant Physiology, submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-H)

OFFICE OF PESTICIDES PROGRAM
REGISTRATION STANDARD BIBLIOGRAPHY
CASE GS0005 ISOPROPALIN

SECTION ONE: Citations Considered to be Part of the Date Base Supporting Registrations Under the Standard

TOXICOLOGY

MRID	CITATION
00002472A	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide [An LD_{50} experiment in the mouse using the technical material]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)
00002472B	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [An acute oral toxicity test in rabbits using the technical material]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)
00002472C	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [An acute oral toxicity test in dogs using the technical material]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)
00002472G	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [An acute oral toxicity test in the chicken using the technical and emulsifiable concentrate]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)
00002472H	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [An acute oral toxicity test in the rat using the technical and emulsifiable concentrate]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)
00002472I	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [A primary eye irritation test in the rabbit using the technical and emulsifiable concentrate]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)

TOXICOLOGY

MRID	CITATION
00002472J	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [A primary dermal irritation test in the rabbit using the technical and emulsifiable concentrate]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)

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REGISTRATION STANDARD BIBLIOGRAPHY
CASE GS0005 ISOPROPALIN

SECTION ONE: Citations Considered to be Part of the Date Base Supporting Registrations Under the Standard

APPENDIX OF CONFIDENTIAL DATA

MRID	Citation
00002591	Decker, O.D.; Frank, R. (1969) Agricultural Analytical Chemistry Method IN-APZ: Determination of EL-179 by GLC: 2,6-Dinitro-N,N- dipropylcumidine. Method dated November 18, 1969. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:091664-B)
05001253	Decker, O.D.; Frank, R. (1974) Determination of the herbicide isopropalin in technical grade material and in formulations. Journal of the Association of Official Analytical Chemists 57(3):645-647.
00002789	Elanco Products Company (1969) EL-179. (Unpublished study received May 4, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:093280-F)
GS005-003	Elanco Products Company (1980) Submission containing a copy of analytical procedure no. 5801677 for nitrosamines and the results of recent analyses on isopropalin

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CASE GS0005 ISOPROPALIN

SECTION TWO: Citations Examined and Judged to be Inappropriate for Use in Developing the Standard

MRID	Citation
00002557	Amundson, M.E. (1972) Radiochemical Studies with ^{14}C-Isopropalin (PAARLAN) on Peppers. (Unpublished study received October 10, 1972 under 2F1278; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091815-A).
00002668	Alban, E.K. (1973) Effect of Certain Herbicide Applications on the Yield of Tomato Cultivar Campbell 28, and Degree of Weed Control: Report No. 40289. (Unpublished study received May 6, 1976 under 3125-277; prepared by CARDC Research, submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-AW)
05001039	Alban, E.K. (1973) Herbicide studies with processing tomatoes--1972. Pages 19-20, In Outdoor Vegetable Crops Research. Wooster, Ohio: Ohio Agricultural Research and Development Center. (Research summary no. 65)
00002632	Alban, E.K. (1973) Herbicide Studies with Processing Tomatoes--1972: Report No. 36931. (Unpublished study received May 6, 1976 under 3125-277; prepared by Ohio Agricultural Research and Development Center, Dept. of Horticulture, submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-G)
05001040	Altman, J.; Campbell, C.I. (1977) Effect of herbicides on plant diseases. Pages 361-385, In Annual Review of Phytopathology. Vol. 15. Edited by Kenneth F. Baker. Palo Alto, Calif.: Annual Reviews.
05001042	Ashton, F.M.; Kukas, R.D. (1974) Relative toxicity of ten dinitroaniline herbicides to six crops. Pages 16-17, In Abstracts of the 1974 Meeting of the Weed Science Society of America; Feb. 12-14, 1974, Las Vegas, Nevada. Champaign, Ill.: Weed Science Society of America.
00002803	Barrentine, J.L. (1969) Experiment No. JLB9-1: [Soil Leaching Data]. (Unpublished study received April 30, 1970 under 0F0968: submitted by Elanco Products., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-O)
00002804	Barrentine, J.L. (1969) Experiment No. JLB9-2: [Soil leaching Data]. (Unpublished study received April 30, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-P)

MRID	Citation
00002514	Benton, D.A. (1972) Herbicide Index on Farm Herbicide Tobacco Tests 1972. (Unpublished study includng letter dated April 17, 1972 from D.A. Benton to John A. Keaton received April 2, 1973 under 1471-79; prepared by Clemson Univ., [Dept. of] Agronomy and Soils, Pee Dee Experiment Station; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024957-E)
00002525	Benton, D.A.; Arnett, J.D. (1973) Tobacco Nematocide, Herbicide Tank Mix on Farm Text Demonstration 1973. (Unpublished study including letter dated November 20, 1973 from D.A. Denton to John A. Keaton, received July 22, 1974 under 1471-79; prepared by Clemson Univ., Cooperative Extension Service, [Dept. of] Agronomy and Soils and [Dept. of] Plant Pathology; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024956-F)
05001043	Beste, C.E. (1974) Weed Control in transplanted tomatoes. Pages 265-269, In Proceedings of the Twenty-eighth Annual Meeting of the Northeastern Weed Science Society. Vol. 28. Salisbury, Md.: University of Maryland Vegetable Research Farm.
05013065	Brathwaite, R.A.I. (1978) Effect of Herbicides on Weed Control Yield and Quality of Eggplant (Solanum Melongena L.) in Trinidad. Weed Research 18(4):243-246.
05001044	Bianco, V.V.; Magnifico, V. (1974) Risultati di esperienze sul diserbo chimico della melanzana. [Results of experiments on chemical weed killers for eggplants] Rivista di Agronomia 8(2/3):311-316.
05000993	British Crop Protection Council (1974) Pesticide Manual: Basic Information on the Chemicals Used as Active Components of Pesticides. Edited by H. Martin and C.R. Worthing. 4th ed. London, England: British Crop Protection Council.
05001252	Buczacki, S.T. (1973) The effects of trifluralin and related dinitroaniline herbicides on clubroot of Brassicae. Annals of Applied Biology 75(1):25-30.
05001045	Burgis, D.S. (1971) Herbicide tests on tomato transplants and seeded tomatoes. Pages 198-205, In Proceedings--Southern Weed Science Society. Vol. 24. Athens, Ga.: Southern Weed Science Society.
00002642	Burgis, D.S. (1972) Gulf States Paper Company Report on Herbicide Studies with the Paper Mulch System of Vegetable Production: Report No. 37725. (Unpublished study received May 6, 1976 under 3125-277; prepared by [Univ. of Florida], IFAS [Institute of Food and Agricultural Sciences], Agricultural Research & Education Center, submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-S)

MRID	Citation
05001048	Burgis, D.S. (1972) Herbicide tests on pepper transplants and seeded peppers. Pages 183-186, In Proceedings--Florida State Horticultural Society; 1971. Vol. 84. Lake Alfred, Fla.: Florida State Horticultural Society.
05001047	Burgis, D.S. (1973) Herbicides for the full bed mulch tomato culture system--II: in-the-row. pages 201-204, In Proceedings--Southern Weed Science Society. Vol. 26. Athens, Ga.: Southern Weed Science Society.
05001049	Burgis, D.S. (1974) In-the-row weed control for peppers on full bed mulch. Pages 194-198, In Proceedings--Southern Weed Science Society. Vol. 27. Athens, Ga.: Southern Weed Science Society.
05001050	Chapman, W.H. (1973) Weed control and crop tolerance with various herbicides applied to Florida shade tobacco. Pages 170-172, In Proceedings--Southern Weed Science Society. Vol. 26. Athens, Ga.: Southern Weed Science Society.
05001051	Cialone, J.C.; Braden, D.A. (1971) Evaluation of herbicides for weed control in transplanted and seeded tomatoes. Pages 401-402, In Proceedings of the Twenty-fifth Annual Meeting of the Northeastern Weed Science Society. vol. 25. Farmingdale, N.Y.: Cornell Ornamentals Research Laboratory.
00002500	Collins, W.K.; Hawks, S.N., Jr.; Kittrell, B.U. (1970) Investigation on Response of Flue-Cured Tobacco to EL-179 in 1970. (Unpublished study received February 10, 1972 under unknown admin. no.; prepared by North Carolina State Univ., Agricultural Extension Service, submitted by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:126632-F).
05001053	Collins, W.K.; Hawks, S.N., Jr.; Kittrell, B.U. (1971) Isopropalin and diphenamid for weed control in flue-cured tobacco. Tobacco Science 15:62.
05001766	Collins, W.K.; Hawks, S.N., Jr.; Kittrell, B.U. (1972) Effects of three herbicides on weed control, yield and value of flue-cured tobacco. Tobacco Science 174(21):51-52.
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00002801	Elanco Products Company (1968) Experiment No. GM8-41X: [Herbicidal Efficacy Data]. (Unpublished Study received Apr. 30, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL;091661-L)
00002814	Elanco Products Company (1968?) Introduction: Degradation of EL-179 [Herbicidal Efficacy Data]. (Unpublished study received April 30, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-AA)
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00002755	Elanco Products Company (1969) Experiment No. ODH9-17 [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-BP)
00002694	Elanco Products Company (1969) EL-179 as a Preplant Application for Preemergence Weed Control in Direct-Seeded and Transplant Tomatoes. Summary of studies 092119-B through 092119-BT. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-A)
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00002817	Elanco Products Company (1969) Decomposition in Rumen. (Unpublished study received October 12, 1969 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091660-A)

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00002818	Elanco Products Company (1969) Decomposition in Soil. (Unpublished study received October 12, 1969 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091660-B)
00002745	Elanco Products Company (1969) Experiment No. CDH9-8: [Herbicidal Efficacy Data]. (Unpublished study received April 9, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092119-BD).
00002598	Elanco Products Company (1969) Isopropalin Recovery from Soil. (Unpublished study received April 26, 1971 under 1471-EX-32; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091664-I)
00002802	Elanco Products Company (1969) Experiment No. GM8-55X: [Herbicidal Efficacy Data]. (Unpublished study received April 30, 1970 under OF0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-M)
00002808	Elanco Products Company (1969) Summary of Experimental Data. (Unpublished study received April 30, 1970 under 0F0968; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091661-T)
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00002617	Elanco Products Company (1970?) Supplemental Field Data: [EL-179]. Summary of studies 091664-AC through 091664-AI. (Unpublished study received Apr. 26, 1971 under 1471-EX-32; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091664-AB)
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00002502	Elanco Products Company (1970) Experiment No. H-32-70-H-13k: Weed Control in Tobacco. (Unpublished study received February 10, 1972 under unknown admin. no.; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:126632-H).
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00002620	Eli Lilly and Company (1971) Isopropalin--Tomatoes: Determination of Free and Conjugated Isopropalin--2,6-Dinitro-N-propylcumidine; 2,6-Dinitrocumidine; 4-Hydroxy-3,5-dinitrocumene--in Tomatoes. (Unpublished study received February 12, 1971 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:091663-A).00002558Eli Lilly and Company (1971) EL-179--Peppers: EL-179 (2,6-
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00002510	Elanco Products Company (1973) Paarlan in Tank-Mix Combination with Certain Soil Incorporated Insecticides and/or Nematocides for Weed, Insect and/or Nematode Control in Transplant Tobacco. Summary of studies 024957-B through 024957-L. (Unpublished study received April 2, 1973 under 1471-79; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:024957-A)
00002509	Eli Lilly and Company (1973) Rotation Crops--Paarlan®: Residue Data on Crops Grown in Rotation on Paarlan Treated Fields. Includes method no. 5801590 dated January 17, 1974. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006925-A)
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00002534	Elanco Products Company (1975) Delayed Incorporation of Paarlan-6EC for Preemergence Weed Control in Flue-Cured Tobacco. CDL:224666-A.
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00002561	Elanco Products Company (19??) Paarlan® E.C. as a Preplant Application for Preemergence Weed Control in Direct-Seeded and Transplant Peppers. Summary of studies 092108-E through 092108-AZ. (Unpublished study received June 6, 1972 under 2F1278; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:092108-A)
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00002560	Elanco Products Company (19??) Reasonable Grounds in Support of the Petition: [Paarlan E.C.]. (Unpublished study received June 7, 1972 under 2F1278; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:095166-B)
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000002768	Elanco Products Company (19??) Paarlan (EL-179) as a Preplant Application for Preemergence Weed Control in Transplant Tobacco. Summary of studies 006401-B through 006401-AB and 006401-AD. (Unpublished study including map, received May 25, 1972 under 1471-79; prepared by Elanco Products Co., Div. of Eli Lilly and Co.; CDL:006401-A)

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MRID	Citation
00002589	Hooks, R. (1970) Evaluation of Pre-plant Herbicides on Transplanted Chile at Los Lunas, New Mexico, 1970: Table 2. (Unpublished study received June 6, 1972, under 2F1278; prepared by [New Mexico State Univ., Middle Rio Grande Branch Experiment Station], submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:092108-AZ)
05012595	Huffmann, J.B.; Camper, N.D. (1978) Growth Inhibition in Tobacco (Nicotiana Tabacum) Callus by 2,6-Dinitroaniline herbicides and Protection by D-Alpha-Tocopherol Acetate. Weed Science 26(6):527-530.
00002806	Humphreys, W.H. (1969) Experiment No. WHH9-27: [Soil leaching Data]. (Unpublished study received April 30, 1970 under OF0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-R)
00002614	Humphreys, W.H. (1970) Experiment No. WHH9,0-28: [Herbicidal Efficacy Data]. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-Y)
05001062	Jaques, G.L.; Harvey, R.G (1974) A simple bioassay technique for dinitroaniline herbicides in soils. Page 93, In Proceedings of the North Central Weed Control Conference; December 3-5, 1974, St. Paul, Minnesota. Vol. 29. Lincoln, Nebr.: North Central Weed Control Conference.
00002767	Johnson, W.S.; Decker, O.D. (1976) Isopropalin: [Chapter 24]. Pages 375-379, In Government Regulations, Pheromone Analysis, Additional Pesticides. Edited by G. Zweig and J. Sherma. New York: Academic Press. (Analytical methods for pesticides and plant growth regulators, Vol. VIII; also In unpublished submission received July 19, 1976 under 476-1615; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:225188-H)
00002593	Johnson, W.S.; Donoho, A.L. (19??) Stability of Isopropalin in Tomato Fruit During Storage. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-D)
00002533	Jones, M.I. (1976) Delayed Incorporation of Paarlan 6EC for Pre-emergence Weed Control in Flue-Cured Tobacco. (Unpublished study received Feb. 23, 1977 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:228098-A)

MRID	Citation
00002494	Keaton, J.A. (1969) Experiment No JAK9-10: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-O)
00002548	Keaton, J.A. (1969) Experiment No. JAK9-10: [Herbicidal Efficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-I)
00002549	Keaton, J.A. (1969) Experiment No. JAK9-11: [Herbicidal Efficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:126687-J)
00002555	Keaton, J.A. (1969) Experiment No. JAK9-15: [Herbicidal Efficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:126687-C)
00002495	Keaton, J.A. (1969) Experiment No. JAK9-11: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-R)
00002492	Keaton, J.A. (1970) Experiment No. JAK0-12: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-O)
05001064	Keaton, J.A.; Webster, H.L. (1970) EL-179--a new soil incorporated herbicide for tobacco. Pages 106-114, In Proceedings--Southern Weed Science Society. Vol. 23. Athens, Ga.: Southern Weed Science Society.
00002784	Keaton, J.A. (1970) Experiment No. JAK0-13: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:006401-Q)
00002785	Keaton, J.A. (1970) Experiment No. JAK0-14: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:006401-R)
00002499	Keaton, J.A. (1970) University Research Report: [Herbicidal Efficacy Data]. (Unpublished study received Feb. 10, 1972 under unknown admin. no.; prepared in cooperation with North Carolina State Univ., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:126632-E)

MRID	Citation
00002782	Keaton, J.A. (1971) Experiment No. JAKO-3: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:006401-C)
00002783	Keaton, J.A. (1971) Experiment No. JAKO-12: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind., CDL:006401-P).
00002519	Keaton, J.A. (1972) University Report: November 9, 1972. (Unpublished study received April 2, 1973 under 1471-79; prepared in cooperation with Virginia Polytechnic Institute and State Univ., Dept. of Plant Pathology and Physiology, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024957-J)
00002490	Keaton, J.A. (1972) Experiment No. JAK1,2-10: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-M)
00002511	Keaton, J.A. (1972) University Research Report: November 11, 1972. (Unpublished study received April 2, 1973 under 1471-79; prepared in cooperation with North Carolina State Univ., Dept. of Crop Science, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024957-B)
00002513	Keaton, J.A. (1972) University Research Report: October 28, 1972. (Unpublished study including addendum and letter dated April 17, 1972 from D.A. Benton to John A. Keaton, received April 2, 1973 under 1471-79; prepared in cooperation with Clemson Univ., Dept. of Agronomy and Soils, Pee Dee Experiment Station, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024957-D)
00002526	Keaton, J.A. (1973) University Research Report: November 2, 1973. (Unpublished study received July 22, 1974 under 1471-79; prepared in cooperation with Virginia Polytechnic Institute and State Univ., Dept. of Plant Pathology and Physiology, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024956-G)
00002524	Keaton, J.A. (1973) University Research Report: November 26, 1973. (Unpublished study received July 22, 1974 under 1471-79; prepared in cooperation with Clemson Univ., Pee Dee Experiment Station, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024956-E)

MRID	Citation
00002821	Massey, G.D. (1970) Experiment No. GDMO-13: [Herbicidal Efficacy Data]. (Unpublished study received June 15, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:093280-AK)
00002623	Mobil Chemical Company (1972) Discussion and Summary of Wireworm Control Data. (Unpublished study received August 17, 1973 under 2224-44; CDL:010068-A)
00003419	Mobil Chemical Company (1977) Summary of Efficacy Data: Modown 80WP—Tobacco. (Unpublished study received January 27, 1978 under 2224-EX-14; CDL:232747-A)
00003529	Mobil Chemical Company (1977) Summary of Large Scale Efficacy Data: Tobacco. (Unpublished study received February 9, 1978 under 2224-50; CDL:232880-E)
00004192	Mobil Chemical Company (1977) Weed Control in Tobacco. (Unpublished study received Feb. 9, 1978 under 2224-50; prepared by [Univ. of Tennessee], Tobacco Experiment Station and Highland Rim Experiment Station, submitted by Mobil Chemical Co., Industrial Chemicals, Richmond, Va.; CDL:232880-D)
05013493	Moore, L.D. (1979) Effect of Air Pollutants on Growth and Yield of Forest Trees, Ornamentals and Field Crops Abstract No. 10.07611. Toxicology Research Projects Directory. Section 1 4(10):86.
05001071	Moreland, D.E.; Farmer, F.S.; Hussey, G.G. (1972) Inhibition of photosynthesis and respiration by substituted 2,6-dinitroaniline herbicides. I. Effects on chloroplast and mitochondrial activities. Pesticide Biochemistry and Physiology 2(3):342-353.
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05001073	Ogle, W.L. (1972) Performance of several herbicides for weed control in transplanted tomatoes and peppers. Pages 203, In Proceedings--Southern Weed Science Society. Vol. 25. Athens, Ga.: Southern Weed Science Society.
00002594	Page, J.G (1968?) Metabolism of 70379 (EL 179) in Dogs, Rats, and Mallard Ducks. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-E)
00002539	Parka, S.J. (1975) Composition of the Liquid Fertilizers Used in the Herbicide-Liquid Fertilizer Research Program. (Unpublished study received September 29, 1976 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:223273-C)
00002540	Parka, S.J. (1975) Experiment No. PA5-088F: [Herbicidal Efficacy Data] (Unpublished study received September 29, 1975 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:223273-D)
05001076	Parochetti, J.V.; Dec, G.W., Jr. (1978) Photodecomposition of eleven dinitroaniline herbicides. Weed Science 26(2):153-156.
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05001079	Raulston, J.C.; Waters, W.E. (1972) Use of herbicides in ornamental flower production under sub-tropical conditions. Pages 229-238, In Proceedings of the XIX Annual Meeting of the Tropical Region, American Society for Horticultural Science; July 18-24, 1971, Managua, Nicaragua. Vol. 15. Edited by D. Rios-Castano.
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05002552	Rodriguez, E.B.; Worsham, A.D. (1973) Herbicides for flue-cured tobacco. II. Soil persistance. Tobacco Science 17:170-174.
05001081	Rodriguez, E.B.; Worsham, A.D. (1973) Herbicides for flue-cured tobacco. I. Weed control, methods of soil incorporation, yield and value of tobacco. Tobacco Science 175(24):57-60.
05001083	Romanowski, R.R.; Libik, A.W. (1978) Soil persistence of isopropalin, nitralin and trifluralin. Weed Science 26(3):258-261.
00002659	Schweers, V.H. (1973) Fresh Market Transplant Tomatoes: Weed Control Trial--Hotcapped: Report No. 39493. (Unpublished study received May 6, 1976 under 3125-277; prepared by Univ. of California, [Agricultural Extension Service], Tulare County Farm Advisor in cooperation with Majarian Brothers, submitted by Mobay Chemical Corp., Agricultural Chemicals Div., Kansas City, Mo.; CDL:224187-AM)
00002543	Shoop, G.J. (1969) Experiment No. GJS9-16: [HerbicidalEfficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-C)
00002544	Shoop, G.J. (1969) Experiment No. GJS9-17: [Herbicidal Efficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-D)

MRID	Citation
00002556	Shoop, G.J. (1969) Experiment No. GJS9-18: [Herbicidal Efficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-R)
00002545	Shoop, G.J. (1969) Experiment No. GJS9-22: [Herbicidal Efficacy Data]. (Unpublished study received January 8, 1970 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-F)
00002777	Shoop, G.J. (1970) Experiment No. GJS0-18: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-J)
00002778	Shoop, G.J. (1970) Experiment No. GJS0-19: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-K)
00002611	Shoop, G.J.; Strait, A. (1970) Experiment No. GJS9, 0-12: [Soil Persistence Data]. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-V)
00002776	Shoop, G.J. (1971) Experiment No. GJS0-17: [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-I)
00002553	Shoop, G.J.; Newman, R. (1969) Havana 52 Dark Tobacco: Plots Treated: June 16, 1969; Tobacco Transplanted: June 24, 1969. (Unpublished study received January 8, 1974 under 1471-EX-32; prepared in cooperation with Univ. of Wisconsin, Arlington Experiment Station, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-O)
05001085	Short, T.H.; Alban, E.K.; Kretchman, D.W. (1973) An evaluation of chemical weed control with early direct seeded tomatoes. Pages 17-18, In Outdoor Vegetable Crops Research. Wooster, Ohio: Ohio Agricultural Research and Development Center. (Research Summary No. 65)
00002552	Slack, C.H. (1969) [Burley Tobacco]. (Unpublished study including letter dated December 11, 1969 from C.H. Slack to George J. Shoop, received January 8, 1970 under 1471-EX-32; prepared by Univ. of Kentucky, Cooperative Extension Service, Dept. of Agronomy; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-M)

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00002497	Smiley, J. (1970) Insecticide-Herbicide Compatibility on Tobacco. (Unpublished study received February 10, 1972 under unknown admin. no.; prepared by Univ. of Kentucky; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126632-A)
05001086	Southwick, L.M.; Willis, G.H.; Dasgupta, P.K.; Keszthelyi, C.P. (1976) The polarographic reduction of some dinitroaniline herbicides. Analytica Chimica Acta 82(1):29-35.
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00002760	Stauffer Chemical Company (1975) Tillam 6-E Residue Data on Wisconsin Cigar Binder Tobacco (Types 54 and 55). (Unpublished study received July 19, 1976 under 476-1615; CDL:225188-A)
05001087	Stevenson, M.R. (1977) Evaluation of herbicides for direct-seeded tomatoes. Pages 106-112, In Proceedings of the 30th New Zealand Weed and Pest Control Conference. Hamilton, New Zealand: New Zealand Weed and Pest Control Conference, Ruakura Agricultural Research Centre.
00002551	Strait, A.O.; Shoop, G.J. (1969) Burley No. 10 Tobacco: Plots Treated: June 5, 1969; Tobacco Transplanted: June 6, 1969. (Unpublished study received January 8, 1970 under 1471-EX-32; prepared in cooperation with Univ. of Kentucky, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126687-L)
05012596	Sung, S.J.S.; Moore, L.D. (1979) The Influence of Three Herbicides on the Sensitivity of Greenhouse-Grown Flue-Cured Tobacco (Nicotiana Tabacum) Plants to Ozone. Weed Science 27(2):167-173.
05001092	Talbert, R.E. (1973) Herbicides for transplanted tomatoes. Arkansas Farm Research 22(5):8.

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05001089	Talbert, R.E.; Frans, R.E. (1972) Comparisons of dinitroanilines in row crops in Arkansas. Pages 38, In Proceedings--Southern Weed Science Society. Vol. 25. Athens, Ga.: Southern Weed Science Society.
05001091	Talbert, R.E.; Kennedy, J.M.; Kennedy, M.R.; Ramthun, L.E. (1974) Field Evaluation of Herbicides in Vegetable Crops, 1974. Fayetteville, Ark.: Agricultural Experiment Station. (Mimeograph series no. 227)
05001093	Tappan, W.B.; Littell, R.C.; Dickson, D.W.; Sanden, G.E.; Lundy, H.W. (1977) Interaction of pesticides used in a pest management study on flue-cured tobacco in Florida. Pages 175-178, In Proceedings--Soil and Crop Science Society of Florida. Vol. 36. Gainesville, Fla.: University of Florida.
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00002798	Watson, J.H. (1969) Experiment No. JHW9-21X: [Soil Persistence Data]. (Unpublished study received April 30, 1970 under 0F0968; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091661-H)
00002613	Watson, J.H. (1970) Experiment No. JHW9,0-21: Soil Persistence Compound EL-179. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-X)
00002486	Webster, H.L. (1969) Experiment No. HLW9-1: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; Indianapolis, Ind.; CDL:005589-I)

MRID	Citation
00002489	Webster, H.L. (1969) Experiment No. HLW9-14: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-L)
00002779	Webster, H.I. (1970) Experiment No. HLWO-3; [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-L)
00002780	Webster, H.I. (1970) Experiment No. HLWO-4; [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-M)
00002781	Webster, H.I. (1970) Experiment No. HLWO-5; [Herbicidal Efficacy Data]. (Unpublished study received May 25, 1972 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:006401-N)
05001097	Webster, H.L.; Cooper, R.B.; Helmer, J.D.; Hobbs, C.D.; Humphreys, W.H. (1970) EL-179: a new soil incorporated herbicide for direct-seeded and transplant tomatoes and peppers. Pages 167-180, In Proceedings--Southern Weed Science Society. Vol. 23. Athens, Ga.: Southern Weed Science Society.
00002622	Webster, H.L. (1970) Experiment No. HLW0-3: [Soil Persistence Data]. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-AL)
00002484	Webster, H.L. (1971) Experiment No. HLW0-3: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-G)
00002485	Webster, H.L. (1971) Experiment No. HLW0-4: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianpolis, Ind.; CDL:005589-H)
00002482	Webster, H.L. (1972) Experiment No. HLW1-11: [Herbicidal Efficacy Data]. (Unpublished study received September 17, 1974 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:005589-E)
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00002592A	West, H.C.; Worth, H.M., ed. (1970) Acute Effects of Compound 70379 in Quail, Ducks, and Goldfish. [Acute oral LD_{50} for bobwhite and Japanese quail using the technical material, study # Q-0-1-70]. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-C).
00002592B	West, H.C.; Worth, H.M., ed. (1970) Acute Effects of Compound 70379 in Quail, Ducks, and Goldfish. [Acute oral LD_{50} for mallards using the technical material, study numbers WF-0-1-70 and WF-0-2-70]. (Unpublished study received April 26, 1971 under 1471-EX-32; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091664-C).
05001098	Wilcox, M.; Currey, W.L. (1975) Chemical control of weeds in field crops. Pages 64, In Annual Research Report of the Institute of Food and Agricultural Sciences, University of Florida, 1973. Gainesville, Fla.: University of Florida.
00002515	Worley, C. (1972) Tobacco Agronomy Test--1972: ASCS #F-718. (Unpublished study received April 2, 1973 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024957-F)
00002501	Worsham, A.D. (1970) Tobacco Weed Control. (Unpublished study including letter dated November 4, 1970 from A.D. Worsham to John A. Keaton, received February 10, 1972 under unknown admin. no.; prepared by North Carolina State Univ., Crop Science Dept., submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:126632-G)
00002531	Worsham, A.D.; Rodriguez, E.; Iemons, B. (1972) Annual Report of Tobacco Weed Control Research in 1971. (Unpublished study received June 5, 1974 under 1471-75; prepared by North Carolina State Univ., Dept. of Crop Science, submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:024954-E)
00002472D	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [A 90-day toxicity study in rats using the technical material]. (Unpublished study received Dec. 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)
00002472E	Worth, H.M.; Arthur, B.H.; Anderson, B.C. (1969) Animal Safety Evaluation of EL 179, A New Herbicide. [A 90-day toxicity test in the dog using the technical material]. (Unpublished study received December 19, 1969 under 1471-79; submitted by Elanco Products Co., Div. of Eli Lilly and Co., Indianapolis, Ind.; CDL:091662-A)

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